31

APR 18 2005

Mental Health Association of Greater St. Louis

1905 South Grand Blvd. • St. Louis, Missouri 63104-1542
(314) 773-1399 • Fax: (314) 773-5930 • www.mhagstl.org • E-Mail: mhagstl@aol.com

April 11, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
PO Box 8010
Baltimore, MD 21244-8040

Dear sir or madam:

I am writing concerning the Medicare Competitive Acquisitions Program (CAP) for Part D drugs published in the March 4, 2005 *Federal Register*.

My comments are:

1) CMS **should** include psychiatric medications in Phase I to alleviate barriers to access inherent in the current system.
2) CMS **needs** to define a reimbursement process for vendors that do not require the discontinuance of medications if the mental health consumer cannot afford to pay the copay. Therapy for people with mental illness needs to be persistent or unneeded, costly hospitalizations will follow.

Thank you for your attention to this matter.

Sincerely,

James E. House, II
Executive Director

APR 2 2 2005

InterAct

InterAct of Michigan, Inc.
610 South Burdick Street
Kalamazoo, Michigan 49007

269-381-3700
269-381-3810 Fax

April 18, 2005

Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attention: CMS-1325-P
PO Box 8010
Baltimore, MD 21244-8010

To Whom It May Concern:

RE: Medicare Competitive Acquisition Program for Part B Drugs

As Executive Director for an agency that annually supports over 1,000 adults with mental illness to live successfully in the community, I would like to stress the importance of the inclusion of psychiatric medications in CAP. While medications are never the only service option needed by persons with mental illness, the lack of psychotropics historically leads to higher costs in terms of psychiatric hospitalizations, loss of housing or employment, and a general poor quality of life.

We very much support the inclusion of psychiatric drugs in Phase I of CAP as we're concerned about the barriers to services that may result if they aren't. Furthermore, we are in need of access to long-acting injectable antipsychotics (i.e. Haldol, Prolixin, and Risperdol Consta) as a key part of our strategy for success in serving individuals with the most intractable symptoms and poorest quality of life. Furthermore, we feel inclusion of the pharmacists and the role they play throughout the process of helping mentally ill adults receive the medications they need to build a strong life is critical to the efficacy of the medication services overall. Current requirements force community mental health providers to stock and dispense injectable medications in bulk rather than the transaction being per individual and directed through the pharmacist thereby bypassing the expertise of the pharmacy professional and his/her role monitoring the total medications a person is taking. This is a risk that should not be taken.

We appreciate your support for persons whose lives have been greatly impacted by the signs and symptoms of severe mental illness through inclusion of medications to treat these problems.

Sincerely,

Claudia Wink-Basing

Claudia Wink-Basing
Executive Director
InterAct of Michigan, Inc.

Funded in part by
Kalamazoo Community
Mental Health Services

"Empowering people to succeed."

APR 22 2005

Kalamazoo Community Mental Health Services

Jeff Patton
Executive Director

Administrative Offices
3299 Gull Rd., P.O. Box 63
Nazareth, MI 49074-0063
Phone: (269) 553-8000
Fax: (269) 553-8012

Access Center
418 West Kalamazoo Ave.
Kalamazoo, MI 49007
Phone: (269) 373-6000
(888) 373-6200
Fax: (269) 373-4951

Recipient Rights Office
3299 Gull Rd., P.O. Box 63
Nazareth, MI 49074-0063
Phone: (269) 553-8000
Fax: (269) 553-8120

Services for Adults with Mental Illness
418 West Kalamazoo Ave.
Kalamazoo, MI 49007
Phone: (269) 382-4086
Fax: (269) 381-2385
Fax: (269) 382-0019
TDD: (269) 382-0847
Med. Fax: (269) 553-7106

Services for Adults with Developmental Disabilities
3299 Gull Rd., P.O. Box 63
Nazareth, MI 49074-0063
Phone: (269) 553-8060
Fax: (269) 553-8104
TDD: (269) 553-8100

Services for Children
3299 Gull Rd., P.O. Box 63
Nazareth, MI 49074-0063
Phone: (269) 553-8110
Fax: (269) 553-8124

Training
5288 Gull Road
Gull Crossing Mall
Kalamazoo, MI 49048
Phone: (269) 349-2425
Fax: (269) 349-1336

www.kazoocmh.org

In affiliation with:
Allegan County Community Mental Health Services
Community Mental Health Services of St. Joseph County
Woodlands (Cass) Behavioral Healthcare Network

"To promote mental health services that empower people to succeed."

Memo

April 15, 2005

RE: Competitive Acquisition Program (CAP)

From: Diane Bishop, Claims Manager
Kalamazoo Community Mental Health and Substance Abuse Services

As the Billing Manager for a Medicaid funded four county Mental Health and Substance Abuse Services I would strongly encourage you to include the injectable medications used for the care and treatment of our at risk clientele to the scope of the CAP program. The injectable medication I'm referring to are: Prolxin, Haldol and Risperdol Consta.

With the current regulations the Mental Health Agency has to order, stock, and maintain the billing of these injectable medications in addition to the true scope of our responsibility, administering the medications. This forces us to step outside our scope of care to that of a Pharmacist. It increases our liability to maintain stock and oversee such aspects as expiration dates. It also requires us to accurately dispense the correct dosage as prescribed by the physician while knowing all possible other medications the client may be prescribed and the knowledge of the possible interactions between these medications. Our agency, nor any other Mental Health Board in the state, is large enough to employ a pharmacist to administrate this medication. We are currently forces to purchase the medication in bulk from a local pharmacy, and assume these risks.

For the expedient and clinically appropriate care of these medications I ask that you strongly consider including these in your upcoming CAP policy change and implementation

Mental Health Association

in North Carolina, Inc.

3820 Bland Road • Raleigh, NC 27609 • (919) 981-0740 • Fax: (919) 954-7238

www.mha-nc.org TDD 800-735-2962

April 19, 2005

APR 2 2 2005

To Whom It May Concern;

Greetings on behalf of the Mental Health Association in North Carolina. I am writing in reference to the Medicare Competitive Acquisition Program (CAP).

The Mental Health Association in North Carolina is pleased that the centers for Medicare and Medicaid Services are examining this issue. The citizens of our state and our nation that experience psychiatric disabilities must have access to the newest and most effective forms of medication. We believe that the plans that you are considering under CAP will help to expand the availability of these life-saving medications.

The Mental Health Association would strongly advocate for the inclusion of psychiatric drugs under the CAP program. Additionally, we advocate for the inclusion of psychiatric medications in Phase I of the CAP program. We strongly believe that the availability for consumers will increase for these medications, and you will see numerous benefits to Medicaid, Medicare, and other critical services available to individuals with psychiatric disabilities.

Thank you for allowing me to share on this issue with you.

Sincerely;

John Tote

John Tote
Executive Director

EQUAL HOUSING OPPORTUNITY

35

KALISPELL MEDICAL ONCOLOGY, PLLP

William M. Boehme, M.D. • Board Certified Internal Medicine & Hematology
Karen J. Hunt, M.D. • Board Certified Internal Medicine, Medical Oncology & Hematology
John Alan Ward, M.D. • Board Certified Internal Medicine & Medical Oncology

APR 2 2 2005

April 15, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1325-P
PO Box 8010
Baltimore MD 21244-8010

RE: Competitive Acquisition Program (CAP)
File code CMS-1325-P

Dear HHS,

I was recently provided a copy of the new proposal regarding the Competitive Acquisition Program for drugs under Medicare Part B. The program certainly does appear to have some merit as to the acquisition of medications in a competitive fashion, however, there are many problems and many of these were outlined in the publication that was referred to me. One in particular is the off-label use of medications. Many of the drugs used in oncology were released for one indication, and yet their major use is in other disease states. Currently these drugs are reimbursable if they have compendium listing. That should be addressed in the rules specifically. Likewise, many drugs are obtained through Patient Assistance Programs, at no cost to the patient (or reimbursement to the physician), and apparently this will not be implemented in the CAP.

Certainly the Grievance and Appeals process also must be fully disclosed before this law goes into effect. The drugs acquired will almost always go to "the lowest bidder" and since not all generics are equivalent I think there should be a means where a physician can select the product name directly rather than be at the mercy of a vender to supply any drug in a certain class of medications. Also, there is no mechanism to introduce new drugs, and since these new drugs can be quite expensive there should be a stated means of introduction of new drugs as to when they will become available. The rules on whether drugs are mixed off-site and shipped, or are sent to the physician unmixed, and whether or not mixing and storage charges are reimbursable, should also be addressed prior to activating this new regulation.

210 Sunnyview Ln., Ste. 003 • Kalispell, MT 59901
Phone 406-752-8900 • Fax (406) 752-8909

Although competitive bidding by the government certainly sounds as though it should have some clout in lowering costs, I think there are still many problems that need to be worked out in detail prior to activation of the new rule and regulation.

Sincerely,

William M. Boehme, M.D.
WMB/sgf

36

APR 2 2 2005

NAMI of Washtenaw County

1100 North Main Street Ste. 114 Ann Arbor Michigan 48104

Phone 734.994.6611 Fax 734.998.0163

email: barb@namiwc.org, Web site: www.namiwc.org, FEST: reimar@namiwc.org

April 17, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
PO Box 8010
Baltimore, MD 21244-8010

To: CMS Personnel

I am president of NAMI, National Alliance for the Mentally Ill, in Washtenaw County, Michigan. Our group works to improve the lives of individuals and families affected by mental illness. As we all know, persons affected by mental illness are some of our most vulnerable citizens.

We are writing to support the proposed rule for not exercising the MMA option barring mental health drugs from CAP. We believe it should not be forgotten what a vital part these medications play in many people's lives.

We feel the final rule should include mental health medications under CAP effective January 2006. We also support the creation of a mental health drug category for specialty pharmacy vendors to offer under Part B, CAP, and to support the creation of easy to use rules for dealing with co-pays and reimbursements. People with mental illness are already under enough stress, and should not have to worry about their ongoing care.

This will make it less difficult for physicians to prescribe Part B mental health meds and allow medications to be utilized more efficiently.

On behalf of all the NAMI members of Washtenaw County, we thank you for your time and consideration.

Respectfully yours,

Chuck Hughes

NAMI
The Nation's Voice on Mental Illness

37

APR 2 2 2005

The Providence Center

Peace of Mind in Community Care

April 12, 2005

Mental health and substance abuse care and treatment services for adults, children, adolescents and families

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
PO Box 8010
Baltimore, MD 21244-8010

Dear Sirs,

I am writing to urge CMS to include injectable psychiatric medications in the Competitive Acquisition Program beginning January 1, 2006. These medications include Risperdal Consta, Haldol Decanoate, Prolixin Decanoate, in addition to short acting injectable Zyprexa and Geodon, and they (especially the long acting injectables) are crucial in the practice of psychiatry, as they are effective in helping to manage some of the most severely ill psychiatric patients. These individuals, often as a result of their illness, are unable to take oral medications on a regular basis. Regular use of these medications can help to keep these individual safe in the community and avoid costly hospitalizations.

There is a significant problem in obtaining these medications for many Medicare patients. Mental Health Centers like The Providence Center do not buy and bill medication for these patients because of the many problems entailed in this process. If a patient has Medicaid, he is much more likely to receive an injectable medication. This decision is not always based on clinical considerations, as it involves the ability to access the medication.

Allowing these medications to be included in this new program would likely save money for Medicare (through lower hospitalizations) and add no significant cost to the program. The treatment of persons with serious mental illness is often an afterthought in the design and implementation of medical benefits. I urge you to avoid discriminating against this group and include injectable antipsychotic medications in the CAP program on January 1, 2006.

Thank you for your consideration of this matter.

Sincerely,

Michael A. Silver, M.D.
Chief Medical Officer

Dale K. Klatzker, Ph.D.
President/CEO

Accredited by the Joint Commission on Accreditation of Healthcare Organizations

951 North Main Street, Providence, RI 02904 • (401) 528-0123 • (800) 456-0300 • Fax: (401) 528-0124
www.providencecenter.org • TDD (401) 274-2599

BLUEBONNET TRAILS
COMMUNITY MENTAL HEALTH AND MENTAL RETARDATION CENTER
1009 Georgetown Street, Round Rock, Texas 78664
(512) 255-1720 Fax (512) 244-8401

APR 2 2 2005

April 14, 2005

To: Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1325-P
PO Box 8010
Baltimore, MD 21244-8010

From: Booth O'Quinn, Chief Operating Officer
Bluebonnet Trails Community MHMR Center
1009 N. Georgetown Street
Round Rock, Texas 78664

Subject: Medicare Competitive Acquisition Program and Psychiatric Drugs

Bluebonnet Trails Community MHMR Center annually provides public mental health services to more than 8,000 persons with serious and persistent mental illness in eight counties in central Texas. A significant number of our clients have Medicare; of those many also have Medicaid benefits. Medication therapy is a primary, first-line treatment that is required to address the most serious, debilitating symptoms of mental illness. Effective medication therapy reduces the need for expensive and often traumatic inpatient psychiatric and emergency room treatment; it improves functioning in order that other non-medication therapies may be effective.

The effectiveness of psychiatric medication therapy has dramatically increased in the past decade with the introduction of new drugs for specific mental illnesses. In an effort to control the increased costs of medication therapy with these new drugs, government and health insurance providers have sometimes responded by limiting access to certain effective medications, either through drug formulary restrictions (some drugs not available, or initially available) or though complicated and expensive authorization and billing processes. These cost-control strategies may be short-sighted when the results are use of less effective medications, often increased hospital and emergency room costs, lost employment and wages, increased involvement with law enforcement and other human service agencies, and increased stress for the patient and family.

As an example, there is a relatively new long-acting injectable psychiatric medication that is effective for many clients with Schizophrenia and complicated mood disorders who, through poor judgment or severe disorganization, frequently do not take their oral medication as prescribed. The result is that they deteriorate and require frequent hospital treatment. Access to this particular type of psychiatric medication is currently limited for Medicare and Medicaid patients by reimbursement strategies: it is not available as formulary drug , but is only reimbursable as an office medical procedure where the provider must purchase the medication directly, bill and hope for reimbursement.

Medicare will only reimburse 40% of the drug/procedure cost, because it is for a "mental illness". If the patient also has Medicaid benefits, Medicaid will cover the remaining rate/ cost, but this requires additional billing by the provider. In Texas, if the patient is covered under a managed Medicaid plan, the medical procedure (drug) requires periodic authorization by the managed-care plan, including new authorization whenever there is a medication dosage change. This drug is treated differently than other drugs (much more easily accessible through Medicaid drug vendor or plan programs; it is more costly for the provider who has all the medication and administration cost liability. This can create an access problem to cost-effective treatment.

I applaud your efforts in the Medicare Modernization Act, in the proposed Competitive Acquisition Program (CAP) rules and I would strongly encourage the following, in order to improve access to effective psychiatric treatment for people who have mental illness:

- Include psychiatric drugs in the CAP,
- Include psychiatric drugs in the initial stages of the CAP,
- Ensure that there is a category in Part B drugs that includes mental health medications and that this category includes *long-acting injectable antipsychotic medications*, and
- Address how vendors will handle uncollectible copays and any other reimbursement issues (such as the example I have provided) that threaten initial or continued access to effective psychiatric medication therapy.

APR 25 2005

PARK CENTER Inc
909 EAST STATE BOULEVARD • FORT WAYNE, INDIANA 46805 • 260/481-2700

April 19, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: The Medicare Competitive Acquisition Program (CAP), for Part B Drugs

To Whom It May Concern:

Park Center, Inc. is a Community Mental Health Center located in Fort Wayne, Indiana.

As psychiatrists, we prescribe long-lasting injectables (e.g. Risperdal Consta) to mentally ill patients. Currently, we are spending, on average, about $3,000 - $5,000 per month on these types of medications.

In Fiscal Year 05, 27% of our patients have Medicare. We have found the billing process through Medicare, under the current system, to be time consuming. It appears we will eventually recoup these costs, based upon previous months' billings. However, the proposed CAP program is a better alternative for patients and providers, in the field of mental health, for the following reasons:

1) Specialty Pharmacies would be responsible for carrying the burden of processing claims, thus relieving organizations like ours of incurring up-front costs; and,
2) Psychiatrists (providers) would only be involved in writing prescriptions and administering the drug.

We realize the Centers for Medicare and Medicaid Services (CMS) is requesting public comment on moving away from the current "buy and bill" methodology, and moving toward the Competitive Acquisition Program (CAP).

As psychiatric professionals, we urge CMS:

- To continue your stand in including psychiatric drugs in the final ruling, and **not** to use CMS exclusion authority under the Medicare Modernization Act (MMA).
- To include psychiatric drugs in the initial stages (phase I) of CAP to alleviate barriers to access inherent in the current system.

- To create a *Mental Health* drug category for mental health drugs, including long-acting injectable antipsychotics.
- To address how vendors should handle uncollectible copays and other reimbursement issues which would threaten therapy persistence.

In closing, as psychiatrists working in our community, we see firsthand the effects of limited access to medication and the difficulty of indigent mentally ill clients to maneuver the pharmacy and payment systems to received medications they need. We encourage CMS to not only develop a *Mental Health* drug category, but to also include psychiatric drugs in Phase I, beginning January 1, 2006.

Sincerely,

Dr. Larry H. Lambertson
Medical Director

Dr. Syed R. Mumtaz
Associate Medical Director

Dr. Don A. Marshall, Jr.
Associate Medical Director

Dr. Mohammad Sami
Associate Medical Director

Dr. Vijoy K. Varma
Associate Medical Director

Dr. Houshmand Rezvani
Associate Medical Director

Massachusetts Association For Mental Health, Inc.

130 Bowdoin Street • Boston, Massachusetts 02108 • Telephone (617) 742-7452 • Fax (617) 742-1187 • E Mail infomamh@mamh.org

James Hooley
President
David K. Shapiro
Past-President
Bernard J. Carey, Jr.
Executive Director

April 20, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1325-P
PO Box 8010
Baltimore, MD 21244-8010

Dear Sir/Madam,

I am writing to express our strongest possible support for the inclusion of psychiatric medications in the Competitive Acquisition Program (CAP). Moreover, we think it is important that these medications be included in Phase One and that CMS create a category under Part B that will include long-acting antipsychotics, administered by injection.

For many people with mental illness access to medications represent the best hope for recovery, independence and the opportunity of living in the community. Too often, access has been denied or severely limited by barriers designed to push consumers and the prescribing community towards a "preferred drug" – one so designated out of cost considerations and not through an individual clinical judgment.

Leaving psychiatric medication out of the CAP Program would be another in a long line of signals that mental illnesses are not real or that treatment for these illnesses are not as important as treatment of others. The fact mental health parity in insurance coverage still does not exist in every state, is yet another example of the arbitrary decisions that have been made about mental illnesses, treatment and, indeed, the people who have these illnesses. We hope from the very outset of the CAP Program, psychiatric medications are included and are included in Phase One.

As an advocacy organization, we experience first hand how public policy can often lag behind significant research discoveries and the new knowledge about the brain and about mental illness. For this reason we encourage you to develop a system that is able to respond to new medications and advances in treatment. One step would be the creation of a category under part B that will include long-acting antipsychotics, including those administered by injection. Whether or not treatment through injections becomes a growing trend, particularly in light of the compliance/adherence issues that exist with other medications, is not yet known. However, if it is excluded from the CAP program,

we might never know, and a large number of individuals for whom this form of treatment is beneficial will be denied access.

People with mental illnesses are in a daily struggle with their disease, and, like cancer patients, some will experience recovery, others will go through periods of remission, and for many the illness will never go away. In addition to fighting their illness, people with mental illnesses must fight a stigma so strong and pervasive that a societal attitude seemingly exists that these illnesses result from character flaws. Today, in addition to the illness and the stigma, many people with mental illnesses now have to fight to gain access to the medications they need to live independently.

We believe adoption of a CAP program that pays particular attention to the needs of those with mental illnesses, and is shaped in a fashion that encourages access to medications is critical and will benefit many.

Thank you for your attention to this matter.

Sincerely,

Bernie Carey

Bernard J. Carey, Jr.
Executive Director

Timothy O'Leary

Timothy O'Leary
Deputy Director for Policy & Research

APR 25 2005

Health Care For The Homeless

April 12, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1325–P
P.O. Box 8010
Baltimore, MD 21344 – 8010

Dear Sir or Madame:

I am writing to comment on the Competitive Acquisition Program ("CAP") as part of the Medicare Modernization Act 2006 and the impact it could have for patients we serve at the Recovery Behavioral Health Clinic at Health Care For The Homeless – Milwaukee. We serve a large percentage of patients with Medicare and Medicaid coverage who currently rely on the Medicaid benefit to obtain psychiatric medications that allow them to function in the community and avoid hospitalization and extreme functional impairment. If Mental Health Services, particularly psychiatric medications in both pill and injectable form, are not in included as a pharmacy benefit from implementation, there will be additional barriers put in place that would complicate patient access to necessary treatment.
For our patients eligible for Medicare now or in the foreseeable future, which may be up to on third of our caseload, a second option to the current "buy and bill" would improve patient access to care and significantly simplify the reimbursement process.
Please consider consumer's needs regarding Mental Health medications as a pharmacy benefit option and improving access to care in CAP.

Sincerely,

C. DeSpain, MD
Clinic Nursing

H Behavioral Health Targeted Case Management MHC Clinic CAP Letter

(414) 727-6320 210 West Capitol Drive, Milwaukee, WI 53212 FAX (414) 727-6321

42.

APR 26 2005

NACO National Association of Counties
Counties Care for America

NACBHD
National Association of county Behavioral Health and Developmental Disability Directors

April 22, 2005

By Hand Delivery

The Honorable Mark B. McClellan, MD
Administrator, Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
Attn: CMS-1325-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B, Proposed Rule (CMS-1325-P)

Dear Dr. McClellan:

On behalf of the National Association of County Behavioral Health and Developmental Disability Directors (NACBHD), please consider the following comments and recommendations in response to the proposed rule issued by the Centers for Medicare and Medicaid Services (CMS) regarding implementation of the new Medicare Part B competitive acquisition program (CAP). 70 Fed. Reg. 10,746 (March 4, 2005).

The Extent of County Government and County Sponsored Behavioral Health and Developmental Disability Services in Communities

County governments and county sponsored authorities contribute over $15 billion dollars to behavioral health and developmental disability services. County governments and county sponsored behavioral health authorities in 22 states either directly or indirectly provide the range of behavioral health services (e.g. mental health, addictions service, and mental retardation and developmental disability services) to 70% of the US population. In 18 states, county sponsored behavioral health authorities ensure delivery of substance abuse services to 60% of the US population. County sponsored local authorities are also responsible in 15 states for the delivery of developmental disability services that reach over 50% of the US population.

In addition to these direct responsibilities, county government authority partners (e.g. criminal justice, social services, foster care, schools and the courts) work collaboratively everyday to

"weave together all the categorical federal and state programs" thereby creating and giving meaning to the public safety net. All county governments and county sponsored authorities are public safety net providers in one fashion or another because ***it is these local governments to which residents turn in time of need.***

The National Association of County Behavioral Health Directors

The National Association of County Behavioral Health Directors (NACBHD) is an affiliate of the National Association of Counties (NACo), and, as such, is the official representative of county governments and county sponsored authorities that provide or oversee mental health, substance abuse treatment and/or developmental disability services. NACBHD has over 375 members.

Comments and Recommendations

As you consider how to phase in the CAP program, it is imperative that mental health drugs are included in the initial rollout on January 1, 2006. The sooner mental health drugs are included in CAP, the sooner a major barrier to a person's access to important new technologies in the treatment of mental illness will be removed.

For most individuals with schizophrenia, one of the most serious mental illnesses, atypical antipsychotics have been the standard of care for over ten years. However, these medications have only been available in pill form. Unfortunately, medication compliance is a major issue for this population. The recent approval of long-acting injectable versions of atypical antipsychotics provides physicians with an important new option in the treatment of individuals with schizophrenia.

As you know, under Part B physicians must purchase a drug or biological, administer the drug or biological, and then bill Medicare for reimbursement and the beneficiary and/or supplemental insurance for the applicable coinsurance. While a number of physician specialties have obtained Part B drugs and biologicals in this manner for years, psychiatrists, especially those practicing in community mental health centers (CMHCs), have extremely limited experience with a buy and bill system.

With the introduction of long-acting injectable atypical antipsychotic therapies, these physicians are learning to navigate this administratively complicated reimbursement system. However, given the reluctance of many psychiatrists to use this model, due in large part to the substantial financial exposure a CMHC incurs when it enters into a buy and bill arrangement, many patients are finding it difficult to access these important new therapies.

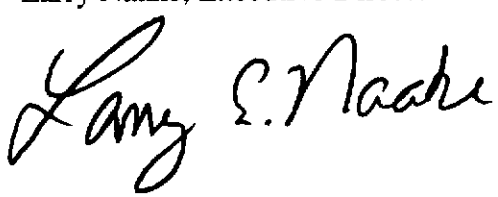
The Medicare Modernization Act recognized that many physicians do not want to be in the business of drug acquisition, and it therefore provided an alternative; namely, CAP. CAP provides physicians with an important option. Under this program, physicians may voluntarily elect to obtain certain Part B drugs from CMS-approved vendors. Physicians will no longer be responsible for submitting a claim for Medicare reimbursement and collecting coinsurance from beneficiaries – that will be the responsibility of the vendors who choose to offer categories of

Part B drugs. For the psychiatrists who choose this option, a major reimbursement and administrative hurdle will be removed, and they will be able to make decisions about different courses of therapy on the basis of the clinical efficacy of a certain treatment.

NACBHD appreciates the opportunity to submit our comments and recommendations to CMS. We look forward to working with you and your staff to ensure that Medicare beneficiaries with mental illness have meaningful access under Medicare Part B to long-acting injectable atypical antipsychotics.

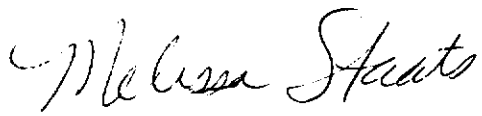
Sincerely,

Larry Naake, Executive Director



National Association of Counties

Melissa Staats, President & CEO



National Association of County Behavioral Health and Developmental Disability Directors

43.

ORIGINAL

APR 26 2005

MGI PHARMA

April 25, 2005

By Hand Delivery

Eric P. Loukas
Senior Vice President, General Counsel & Secretary
MGI PHARMA, INC.
5775 West Old Shakopee Rd., Suite 100
Bloomington, MN 55437-3174
(Direct Phone) 952-406-3181
(Direct Facsimile) 952-406-3281
(Email) eric.loukas@mgipharma.com

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals under Part B, 70 Fed. Reg. 10746 (March 4, 2005) [CMS-1325-P]

Dear Dr. McClellan:

MGI PHARMA ("MGI") respectfully submits the following comments pertaining to the Proposed Rule issued by the Centers for Medicare and Medicaid Services ("CMS") on the Competitive Acquisition of Outpatient Drugs and Biologicals under Medicare Part B (the "Proposed Rule"), 70 Fed. Reg. 10746 (Mar. 4, 2005). The Proposed Rule implements provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") that concern the distribution and payment of drugs under the Competitive Acquisition Program ("CAP"). MGI commends CMS for issuing guidance about the CAP and, in the spirit of cooperation, raises the issues set forth in this comment letter for CMS's consideration.

MGI is an oncology-focused biopharmaceutical company that acquires, develops and commercializes proprietary products that address the unmet needs of cancer patients and is the manufacturer of several products, including Aloxi® (palonosetron hydrochloride) injection (J2469). Aloxi is a differentiated, long-acting selective serotonin-3 (5-HT_3) anti-emetic drug beneficial in preventing nausea and vomiting associated with cancer chemotherapy.

Because a single dose of Aloxi is administered in the physician office setting to prevent nausea and vomiting up to five days and is reimbursed under Medicare Part B, it is important to MGI that CMS develop and implement the CAP required under MMA in a manner that ensures

patient access to life-improving therapies, promotes fairness and equity for physicians, and is consistent with the delivery of care in cost-efficient, patient-friendly settings. MGI's comments address the following areas of concern:

(1) CMS guidance concerning the CAP;

(2) CMS's proposed phase-in of the CAP;

(3) CMS's determination of drug categories;

(4) The confidentiality of manufacturer bid prices under CAP; and

(5) The treatment of manufacturer prices offered under the CAP in the calculation of average sales price ("ASP").

I. Overview of the CAP

MGI commends CMS for acknowledging the need to gather information and obtain industry input on the CAP through the use of an Open Door Listening Session and other informal public processes. MGI strongly encourages CMS to continue to solicit input from the public through the use of these informal means, as well as through the process of formal notice and comment rulemaking, to allow interested parties an equal opportunity to provide specific, detailed guidance to CMS.

II. Categories of Drugs to be Included under the CAP

A. Phasing in CAP Drugs by Physician Specialty

MGI supports CMS's proposed phase-in the CAP on a physician specialty basis and recommends that CMS begin this process with a specialty other than oncology. The CAP represents a significant change in the acquisition and reimbursement of Part B drugs and, for this reason, there undoubtedly will be many unforeseen issues when the CAP becomes operational. CMS can minimize any resulting disruption for Medicare beneficiaries and physicians and remedy any CAP questions and concerns more quickly by starting the phase-in with a physician specialty that typically administers relatively fewer drugs than oncology. MGI also believes that initiating the phase-in with a non-oncology specialty will, on a long-term basis, create a more successful CAP. The payment changes required under the MMA disproportionately have affected oncologists more than other physician specialties. Out of frustration or fatigue, many oncologists may opt not to participate in the CAP if CMS begins the initial phase-in with them. Oncologist rejection of the CAP may unduly influence other physicians to similarly reject the program when CMS implements it more broadly.

B. Determination of Drug Categories

MGI supports the establishment of broad drug categories and has concerns about CMS's proposal to include only those drugs that are "usually" administered by a particular physician

specialty in the initial CAP phase-in. The Proposed Rule indicates that CMS may take one of two approaches to the phase-in of the CAP. Under the first approach, CMS initially would include only those drugs that are "usually" administered by a particular physician specialty whereas, under the second approach, CMS initially would include "all" such drugs. Although it is possible to identify and include only the most commonly used Part B drugs, such a methodology has certain limitations. Most importantly, a drug that has high utilization may not necessarily be the most effective for a particular Medicare beneficiary as determined by the beneficiary and his or her physician. However, exclusion of a drug from a drug category may influence a physician's clinical decision-making and cause the physician to choose a less effective drug that is covered by the CAP. This is especially true given that the purpose of the CAP is to "provide opportunities for physicians who do not wish to be in the business of drug acquisition." 70 Fed. Reg. 10,748. Accordingly, MGI supports the adoption of broad drug categories in the initial phase-in of the CAP that include all drugs administered by a particular physician specialty as necessary to ensure meaningful physician participation in the CAP.

If CMS takes a more limited approach to phasing in the CAP, we urge CMS not to determine drug categories based on historical claims data, as suggested by CMS's inclusion of the drugs in Table 1. Such data does not acknowledge physician use of more recently approved drug therapies that may result in improved clinical outcomes, overall reductions in the cost of patient care or those that have broader indications than their older predecessors. For example, Aloxi received FDA approval on July 25, 2003 and has an indication for the treatment of delayed nausea and vomiting associated with chemotherapy that other 5-HT_3 anti-emetics do not. This indication is based upon adequate, randomized Phase III clinical trials comparing Aloxi to other 5-HT_3 anti-emetic drugs, in which only Aloxi demonstrated this meaningful clinical benefit to cancer patients. In fact, in CMS's proposed physician fee schedule rule, CMS stated that "Even though we do not have a code or volume for [Aloxi] from 2003 [. . .] it is the highest growth injectable antiemetic drug currently on the market." 69 Fed. Reg. 47,562 (Aug. 8, 2004). However, if CMS were to determine "typically administered" 5-HT_3 anti-emetics based solely on 2003 claims data, Aloxi likely would be excluded from the CAP. This result would be inconsistent with more current data and is only one example of potentially negative and unwarranted drug exclusion. We believe it would be more appropriate and equitable for CMS to use more current data to establish drug categories. If CMS adopts a more limited phase in approach in establishing drug categories we also recommend that CMS outline the process in the final rule for including all drugs under the CAP within an established time period.

C. Confidentiality of Manufacturer Bid Prices

MGI requests that CMS incorporate into the CAP regulations explicit provisions to protect the confidentiality of manufacturer bid prices submitted under the CAP. Pricing information is extremely sensitive within any competitive industry, and its release often has adverse consequences. The Proposed Rule does not address the confidential nature of manufacturers' pricing information or include safeguards to protect such information from disclosure. Commercially sensitive pricing information clearly falls within exemptions under the

Freedom of Information Act[1] and the Trade Secrets Act.[2] We therefore request that CMS address this issue in the final rule by detailing the specific steps the agency will take to protect the confidentiality of manufacturer bid prices submitted under the CAP from public disclosure.

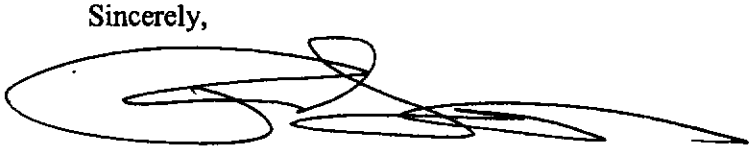
D. Exclusion of Manufacturer Prices Offered Under the CAP from the Calculation of ASP

MGI requests that CMS exclude manufacturer prices offered under the CAP from the calculation of ASP. The Proposed Rule does not address the treatment of such prices; therefore, presumably they must be included in ASP. Such inclusion may cause manufacturers to limit the price concessions they make available to CAP vendors, however, and could materially affect the ability of the CAP to "provide opportunities for federal savings" as contemplated in the Proposed Rule. 70 Fed. Reg. 10748. Higher CAP prices would also increase costs to Medicare beneficiaries who would continue to be responsible for copayment amounts under the CAP. Therefore, we request that CMS issue guidance in the final rule that excludes manufacturer bid prices from the calculation of ASP, to the extent CMS determines it has such authority.

* * * *

MGI appreciates this opportunity to present these comments to CMS. We hope our general recommendations will be useful to CMS in developing policies that will improve the CAP. If you have any questions or need additional information, please do not hesitate to contact me at 952.406.3181.

Sincerely,



Eric Loukas
Senior Vice President, General Counsel & Secretary

1 5 U.S.C. § 552(b)(4); 45 C.F.R. § 5.65.
2 18 U.S.C. § 1905.

APR 26 2005

44

LOMA LINDA UNIVERSITY ADVENTIST HEALTH SCIENCES CENTER

Office of the President

11175 Campus Street
Loma Linda, California 92354
(909) 558-7570
Fax (909) 558-7929

April 22, 2005

Mark B. McClellan, M.D., Administrator
Center for Medicare Management
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: **California Heart and Surgical Hospital**

Dear Administrator McClellan:

I am writing to you regarding a matter of urgent concern. You are undoubtedly aware of the proposed development of a specialty hospital in Loma Linda, California by a group of physicians and other investors. The hospital would be known as "California Heart & Surgical Hospital" and would specialize in cardiovascular and orthopedic surgical services. The development of this hospital threatens the health and welfare of California residents and jeopardizes Loma Linda University Medical Center's ability to continue its dedicated mission of service to those in need. In addition, these developments raise concerns of national scope under the federal self-referral prohibitions (the "Stark Law") and the accompanying specialty hospital moratorium.

It appears that the promoters of this project are seeking to circumvent the Stark Law moratorium on specialty hospitals, and have submitted an advisory opinion request to CMS in furtherance of this purpose. Although we are not privy to the specific arguments that the promoters may have made in their request for an advisory opinion, we are generally aware that the promoters have asserted the position that the proposed hospital does not meet the definition of "specialty hospital" because it will have a single emergency department bed and perhaps offer some treatment for ear, nose and throat ailments. Alternatively, they appear to be arguing that the proposed hospital is "grandfathered" under the specialty hospital moratorium by virtue of having been "under development" as of November 18, 2003.

The facts that are known to the Loma Linda community refute both of these contentions. As such, we respectfully request your consideration of the following arguments, and the supporting facts:

1. **The Proposed Hospital is a "Specialty Hospital" Subject to the Moratorium.** As you are aware, under the moratorium, the "whole hospital" exception is not available to specialty hospitals. The Stark Law generally provides that a "specialty hospital" is a hospital that is primarily or exclusively engaged in the care and treatment of one of the following categories: (a) patients with a cardiac condition; (b) patients with an orthopedic condition; (c) patients receiving a surgical procedure; and (d) any other specialized

category of services that the Secretary of DHHS designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital.[1]

The promoters of this project appear to be asserting the position that the proposed hospital does not meet the definition of "specialty hospital" because it will have a single emergency department bed and perhaps offer some treatment for ear, nose and throat ailments. By providing a very narrow subset of non-surgical or non-cardiac services, the physician investors are attempting to circumvent the moratorium, and engage in the very referrals that Congress has seen fit to halt, pending further analysis and consideration. In a letter from Herb Kuhn to the California Healthcare Association dated December 21, 2004, in reference to whether a limited service hospital that operates a part-time emergency department that may not be fully staffed or equipped to treat the full spectrum of emergency patients, Herb noted that "we believe the operation of such an emergency department would tend to indicate that the hospital is a specialty hospital to which the moratorium would apply."

In our view, the primary purpose of the proposed hospital is to provide cardiovascular and orthopedic services. In fact, the proposed hospital will hold itself out to the public as a specialty hospital. Its very name -- "California Heart & Surgical Hospital" -- makes clear its primary purpose -- *i.e.*, the provision of cardiac and surgical services. Note, that as further evidence of the project promoters' true intent, the original corporate name was "Loma Linda Specialty Hospital," which was changed shortly after Congress passed the moratorium -- in March, 2004. Furthermore, in a press released issued on April 5, 2004, the spokesperson for the hospital states that "the hospital will offer multi-specialty surgical services and post-surgical recovery care in a comfortable, home-like environment." By the spokesperson's own words, we can see that the primary focus of the hospital will be on specialized surgical services.

Thus, it is our contention that a hospital that looks like a specialty hospital (*i.e.*, by its name) and acts like a specialty hospital (*i.e.*, primarily providing specialty services and derives the majority of its revenues from those services) -- is in fact a specialty hospital. As such, we would urge CMS to recognize this, and conclude that the proposed hospital is in fact a "specialty hospital" within the Stark Law definition.

2. **The Proposed Hospital is not "Grandfathered."** As you know, a "grandfathered" specialty hospital is one that CMS determines was in operation or "under development" as of November 18, 2003 and for which: (a) the number of physician investors has not increased since that date; (b) the specialized services furnished by the hospital has not changed since that date; and (c) any increase in the number of beds has occurred only on the main campus of the hospital and does not exceed the greater of 5 beds or 50 percent of the beds in the hospital as of that date.[2] In this regard, we have heard anecdotal reports that physicians have been approached well after November 18, 2003 to invest in this project. Moreover, we have a copy of the executive summary of the private placement memorandum dated April 14, 2004, in which the project organizers were offering membership units in the project. As for the scope of services to be offered, we have been informed by inside sources that the scope of the specialized services to be offered continues to grow. Based on newspaper reports, we know that the initial projected cost of the project was expected to be $40 million, but now exceeds $60 million. Further, newspaper reports indicate that it was initially contemplated that the hospital would have 24 beds, but is now approaching 35 beds. We have seen this project continue to evolve and grow over the last 18 months in a manner that leads us to only one conclusion -- that as of November 18, 2003, the project was still only in preliminary stages of planning.

[1] 42 U.S.C. §1395nn(h)(7)(A) (emphasis added). Excluded from this definition are psychiatric hospitals (defined under 42 U.S.C. §1395x(f) - "primarily engaged in providing . . . psychiatric services"), rehabilitation hospitals (as defined by the Secretary), children's hospitals ("inpatients predominantly under 18 years"), long-term care hospitals ("average inpatient length of stay . . . greater than 25 days"), and certain cancer hospitals.

[2] 42 U.S.C. §1395nn(h)(7)(B).

In determining whether a specialty hospital was "under development" as of November 18, 2003, we understand that CMS considers whether the following had occurred as of that date: (w) architectural plans were completed; (x) funding was received; (y) zoning requirements were met; and (z) necessary approvals from appropriate State agencies were received.[3]

With respect to the completion of architectural plans, even if the investors had *begun* to draw up plans before November 18, 2003, the plans cannot be considered "complete" until the State of California Office of Statewide Health Planning and Development (OSHPD) reviews and approves them. We understand that the hospital's *preliminary* architectural plans were not even submitted to OSHPD until Spring, 2004, and that no formal approval of the project has yet been provided. In fact, "Hospital Vision" (which appears to be the specialty hospital's newsletter) in Volume 1, Issue 1 dated June 1, 2004, includes an article entitled "Hospital Design Nearing Completion." The article notes, "several meetings have been held during which walls have been repositioned, whole departments moved, and at one point, the hospital itself relocated. Out of this dynamic process has emerged a very exciting design that will be completed for an OSHPD submittal at the end of June." In Volume 1, Issue 2 of the newsletter dated July 2004, an article notes that "hospital leaders looked to include OSHPD in the very initial phases of the design process. Not just team members but the entire hospital development team met with OSHPD representatives in April 2004 for consultation regarding the project and early insight and feedback regarding OSHPD expectations." This demonstrates that discussions held in April, 2004 by the project organizers were, by their own words, considered to be "early." Most certainly, architectural and design plans were still being revised well after November 18, 2003 – in fact it appears they were incomplete as much as 8 months after that date if not longer.

With respect to the receipt of funding, we understand that there had been only partial funding as of November 18, 2003, and that developers were still seeking investment after that date. We have received anecdotal reports of individuals who were in fact solicited to invest in the project after that date. As noted above, an executive summary dated April 14, 2004, reflects that investment was still being sought well after November 18, 2003. We also understand that the project had more recently lost the support of a few of its institutional investors, which would suggest that substantial funding was likely not received by November 18, 2003. With this much funding not having been received by November 18, 2003, there likewise could not have been substantial expenditures made by that date. For example, the "Hospital Vision" newsletter cited above notes that the land purchase was not completed until late 2003, but there is no discussion of any other major expenditures.

With respect to whether zoning requirements were met, we understand that the City of Loma Linda has not approved any required land use permits to date, and that these applications were not even submitted until September 1, 2004.

Finally, with respect to receipt of necessary approvals from State agencies, the hospital's license has not yet been received. As you can see from the attached photographs taken April 22, 2005, construction of the hospital has not begun even to the smallest degree, and it does not appear that any monies have been spent in that regard.

In conclusion, it appears that the investors have little or no basis for arguing that the proposed hospital was under development as of November 18, 2003. Almost 18 months later, all of the critical aspects of the hospital's development are still incomplete. Thus, we urge CMS to conclude that the proposed specialty hospital is not "grandfathered" under the moratorium.

[3] Pub.L. 108-173, Sec. 507(b), Dec. 8, 2003, 117 Stat. 2296.

A number of local and national organizations have already voiced their opposition to this project. The Loma Linda Chamber of Commerce recently voted against providing its support, along with the San Bernardino County Board of Supervisors which have adopted a position of non-support. Others who have joined in voicing their opposition to this project, to name a few, are:

California Alliance for Consumer Protection

California Congress for Seniors

American Association of Business Persons with Disabilities

California Senior Action Network

Democratic Process Center

Consumer Action

Administrator McClellan, this year, Loma Linda University Medical Center will celebrate 100 years of improving the health of the local, national and international communities that we serve. This amazing accomplishment has occurred regardless of difficult circumstances because of a deep commitment to healthcare mission and ministry, the sacrifice and dedication of competent clinicians and staff, the support of our community, and the blessing of God. The development of California Heart & Surgical Hospital, however, will undoubtedly jeopardize our ability to continue this dedicated mission of service, research and education. Therefore, we respectfully request that CMS not allow California Heart & Surgical Hospital to circumvent the Stark Law moratorium.

Thank you for your consideration of this matter. I am immediately available to you should you wish to discuss this matter of critical importance to the future of Loma Linda University Medical Center.

Sincerely,

Lyn Behrens, M.B., B.S.
President

cc: Mr. Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244 -1850

C. Duane Dauner
California Hospital Association
1215 K. Street, Suite 800
Sacramento, CA 95814

415

APR 25 2005

Health Care For The Homeless

April 19, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1325–P
P.O. Box 8010
Baltimore, MD 21344 – 8010

Dear Sir or Madame:

I am writing to express some concerns regarding the Competitive Acquisition Program as part of the Medicare Modernization Act 2006. We at the Recovery Behavioral Health Clinic at Health Care for The Homeless – Milwaukee serve an indigent population, many of whom have Medicare and Medicaid health care coverage. Those with the Medicaid depend on this benefit to be able to have access to the psychiatric medication which allow them to not only functionally live in the community but also to avoid disruptive and costly hospitalization. This not only benefits the individual but is a societal cost benefit compared with the true impact of inpatient hospitalizations. Should Mental Health Services, especially oral and injectable psychiatric medications, not be included as a pharmacy benefit from the outset it would place an avoidable and costly obstacle in patients having access to needed care.

Patients who are eligible for Medicare comprise approximately a third of our caseload. Having a second option to the existing "buy and bill "would enhance a patients' ability to receive care. It would additionally simplify the reimbursement process. It is my hope that patients' needs for psychiatric medications will be given strong consideration as a pharmacy benefit from initial implementation of CAP.

Yours truly,

George Gilman, LCSW - Psychotherapist

(414) 727-6320 210 West Capitol Drive, Milwaukee, WI 53212 FAX (414) 727-6321

SOMERVILLE MENTAL HEALTH ASSOCIATION, Inc.

Caring, Competence, Community

46

April 8, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

Attention: CMS-1325

Dear Sir or Madam:

Psychiatric drugs should be included in the Competitive Acquisition Program, in particular Phase 1 of CAP, to keep these accessible as any other demonstrably crucial medications.

These psychiatric medications, including long-acting injectible anti-psychotics, are vital to ensure the most effective treatment to enable severely impaired individuals to live productive lives in the least restrictive settings. Without them, such individuals are likely to suffer emotional and social deterioration that can be tragic and costly for them, their families and the community.

Thank you for your consideration.

Sincerely,

Peter Lenrow, Ph.D.
Executive Director

Management Services
167 Holland St.
Somerville, MA
02144
617-625-0710

Child & Family Services
63 College Ave.
Somerville, MA
02144
617-629-6628

Mystic Family Counseling
10C Memorial Rd. 16
Somerville, MA
02145
617-629-6617

Adult Services
5 Hall Ave.
Somerville, MA
02144
617-623-3278
Connecting All Sites-TTY

Day Treatment
78 College Ave.
Somerville, MA
02145
617-629-6624

Community Treatment Team
2 Ellsworth St.
Somerville, MA
02145
617-623-5487

Early Head Street
474 Broadway
Somerville, MA
02145
617-629-6652

47

APR 25 2005

MSHO

Michigan Society of Hematology and Oncology

Advocacy - Research - Education

15 April 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: FILE CODE CMS-1325-P
COMMENTS ON THE MEDICARE PROGRAM; COMPETITIVE ACQUISITION OF OUTPATIENT DRUGS AND BIOLOGICALS UNDER PART B

On behalf of our membership of 313 practicing oncologists in the state of Michigan, the Board of Directors of the Michigan Society of Hematology and Oncology (MSHO) would like to comment on the proposed rules as published in the March 4, 2005 Federal Register concerning the implementation of the Competitive Acquisition Program (CAP) with a target date of January, 2006.

Our State Society serves as the voice of 90% of Michigan's community oncologists who have several concerns with the regulations as proposed in the CAP document and with the possible impact these regulations will have on our patients and our practices. As requested in the Federal Register document, we have organized our comments to match the section captions in the document.

- **CATEGORIES OF DRUGS TO BE INCLUDED UNDER CAP**

As we understand this section of the document, CMS is looking for comments on how this program could either be phased in by specialty or drug or whether the program should address all drugs used in the physician setting all at once.

Oncology is the specialty using the most broad and all encompassing drugs covered under Part B. By starting with the largest specialty, CMS may be increasing the likelihood of failure. That is, Oncology brings a tremendous volume of claims into the processing system. If the systems are new and untried, the influx of heavy claim submission could create a backlog and delay reimbursement. In addition, by beginning with the largest specialty, the error rates, claim denials, vendor claims issues, and system problems will be magnified.

3630 ROCKINGHAM - ROYAL OAK, MI 48073
PHONE (248) 549-1440 - (800) 456-3413 - FAX (248) 549-1608 - WEB SITE: WWW.MSHO.ORG

Since CAP will be a totally untried and untested program and that any interruption of a patient's cancer treatment endangers their chance of survival, we suggest that the pilot program be initiated with a smaller specialty with less patient care impact. We realize that possible vendors may not bid on the lower volume drugs, but feel that they would also be better served to move into the arena on a gradual basis as opposed to holding large numbers of unpaid claims in their accounts receivable

▪ COMPETITIVE ACQUISITION AREAS

The MSHO members would like CMS to be very cautious in selecting large areas for a vendor in the CAP initiative. Our concern is that a vendor will bid for the program in multiple areas, complete an RFP that would indicate they were able to handle that geographic area and then be unable to actually fulfill their responsibility. We would hope that CMS will make a very direct effort in the selection process to ensure that the vendor is capable at the outset to meet their obligations as opposed to being in the process of trying to assemble the needed warehousing, staffing and communications networks they require. All should be in place at time of selection and CMS should only consider vendors with the network in place. At least two (2) vendors in each region should be selected to give practices the option to choose the vendor based upon service and vendor commitment.

▪ CLAIM PROCESSING OVERVIEW

The Federal Register publication indicates that CMS feels the requirements of claim processing would place no additional burden on a physician practice under CAP. ***We STRONGLY disagree with the idea that this will place no additional burden on a practice and offer these reasons.***

⇨ Claims to include an "order/prescription number"

When a patient is examined in an office and chemo therapy is indicated, the physician will be required to submit a request to the vendor for the applicable drugs. The vendor creates a unique identification number and assigns it to the drugs upon delivery. It is now the practice's responsibility to inventory the drugs, store them until the patient arrives, makes the notation as to the ID number assigned to the drugs, then to remove them from inventory once the patient is treated and notify the vendor. ***This would be a totally new task for the practice.***

⇨ Inventory Management

In the Federal Register document it states, "we do not believe that separate physical storage of CAP drugs is required. However, we are proposing that physicians participating in the CAP would be required to maintain a separate electronic or paper inventory for each CAP drug obtained." The document indicates that this would not be burdensome to the practice and additional reimbursement would not be made. Our members maintain that this will in fact increase our administrative burden. Currently, most Oncology practices use an inventory cabinet that stores the drugs in the appropriate manner, monitors the drugs in the cabinet, keeps a

minimal amount of inventory on hand, checks the expiration dates and, in many cases interfaces with their practice management system to track usage. ***In whatever form, a separate inventory, not only for a particular carrier but a specific patient, would be required and the matching of drug with the order number would have to be added to the tasks performed by our nursing staff. This would add not only tremendous staff tracking duties but also require many practices to increase the size of their inventory space. Individual patient drugs need to be maintained - a large practice effort is required.***

⇨ ***Ordering Process***

Within the Claim Processing Overview section is contained reference to the actual placement of an order by the physician to the vendor. This area glosses over a few items that need to be addressed. First of all, if the physician places an order and expects to receive only the drugs needed for a particular visit and the vendor ships the drugs for a full course of treatment, how will the physician practice be expected to maintain these drugs in inventory for that patient? The practice would then be compelled to maintain the individual patient's inventory adding significant burden to the office staff. This is not affecting a small number of patients, but every Medicare patient coming in for treatment. This is a significant amount of inventory to maintain. The patient's treatment may change, be discontinued or be delayed for any number of reasons and the drugs are the responsibility of the physician. ***We feel that the vendor must be advised to ship only the amount of drug requested for that patient by their physician.***

This reason then brings up another area of concern we have experienced with other insurance carrier MVI programs. That is, the vendor ships only a partial order and not the complete order. This could be an oversight by the shipment department, could be the result of a problem with the patient's secondary insurance or because of an outstanding patient balance. ***CMS must direct the vendor to not suspend a shipment or parts of a shipment due to billing problems or patient outstanding balance***. This is a major patient safety issue. In each of our practices we have had to deal with secondary insurance problems and patients without financial ability to cover their deductible and copays. It has been our belief that health care should not be denied these patients and we work with them to resolve the issue. We have grave concerns that a vendor will not be equipped to handle nor have the background to work with patient advocacy groups and pharmaceutical companies to secure assistance for these patients. The physician is compelled to treat the patient in a timely fashion and would assume additional responsibility and liability. Should the vendor be allowed to discontinue shipment of a patient's drugs, who will be responsible for telling the patient that they cannot continue with treatment? If the patient's health fails and a lawsuit ensues, who will be held responsible? ***CMS must address these issues of responsibility and liability prior to implementation.***

Although not addressed in this publication, we would like to ask CMS to consider the cost of the supplies used in chemo therapy treatments. Will the physician be responsible for supplying the saline, fluids, needles, bags, tubing, poles, chairs and other sundry items not currently covered by CMS? Will the vendor furnish these items? Current administration reimbursement amounts do not cover the cost of these supplies and any decrease in the fees will be more devastating.

⇨ Information for Vendor

Also included in this section is a list of information that an office would need to supply the vendor in order for the drugs to be shipped. Although we understand that some data is required, we would like to limit the amount of personal information submitted to the vendor and be assured that this falls within HIPAA parameters..

It is our opinion that the only information supplied to the vendor is that information required to submit a claim. That would include insurance information, address/contact information, policy holder information and diagnosis. We feel that any additional information would violate patient confidentiality.

⇨ Submission of Claim

The submission of claims by the physician and the vendor is also addressed in this section. ***The requirement is that the physician is to place the unique ID number for that patient's drugs on the claim form for that date of service.*** This may appear to be an easy requirement but there are complications.

Each practice has a software system that would have to be adjusted and tested in order for the claim form to be submitted in the proper fashion. It may be the intent of CMS to have this information in the note section of the hardcopy claim or in the corresponding area of an electronic submission but this may not be accommodated by several practice management systems. Oncologists are already required to use the note section to indicate the names of NOC drugs, the lab results for the administration of several palliative pharmaceuticals and other pieces of information. The note section is limited to 2 lines. If multiple drugs are administered and the practice is required to indicate each of the drugs, the software systems on our end and the systems on the processing side will have to be adjusted to handle more than the 2 allowable lines. Based upon the recent implementation of HIPAA requirements, the software companies may not be able to handle this change in a timely manner. The same could be said for the processing systems used by CMS and its carriers. This would cause a tremendous delay in the processing of claims as of January 1, 2006 with severe financial penalties to the practice due to delayed reimbursement. ***In addition, we would anticipate that the software vendors would pass along the cost of the system adjustments to the practices and we would be paying for the change out of what little is left as a profit in our practices.*** We feel this would place an unnecessary financial burden on small practices with no additional administrative reimbursement.

The vendor claims cannot be paid until the physician submits a clean claim form including the order/prescription number. Should there be a delay on the part of the physician's office, the vendor cannot bill. The indication in the Federal Register publication is that 14 days to submit a claim would be appropriate. This is based on CMS studies indicating that 75% of physicians are already filing within that time frame.

We would like to bring out the fact that as a small business with decreasing margins, practices may be faced with cutbacks and staff loss. The initial submission of claims may be delayed by computer issues on the submission side and on the processing side. To hold the physician liable for this time lapse would be unfair. To expect the vendor to "lend" CMS the money outstanding in drug costs is also unfair. ***We suggest that CMS reconsider the time benefit from both sides of the claim issue. We would suggest that the physician be allowed 30 days for submission of a clean claim and that the vendor be able to receive partial payment on drugs. The percentage allowed should be discussed as an RFP issue with the vendors leading the discussion.***

⇨ ***Matching Claim Forms***

We also have serious concerns with the method of matching a physician claim with a vendor claim based upon the "order/prescription number." ***Because of the volume of drugs administered in an Oncology practice to a large number of patients, the administrative burden on the practice will increase not decrease.*** When a physician claim is paid and the vendor claim is denied, the first call will be to the physician practice to find out why and to research the error. If the claim submitted by the physician contained an error in the "order/prescription number", a corrected claim would have to be submitted through the normal claim adjudication processes already in place causing yet another delay in reimbursement to be experienced by the physician and the vendor.

⇨ ***Secondary Billing - Patient Responsibility***

This section indicates that the vendor cannot submit a secondary claim or bill the patient unless the primary claim has been paid. We do agree with this requirement but are cautious as well. ***We ask that CMS direct the vendor to not have patients routinely sign an ABN "just in case."*** If this is not made a part of the requirements, ***we are concerned that the vendor would routinely use this as a means of avoiding the follow up and resubmission of secondary claims on the patient's behalf.*** They would have "a way out" of billing issues that would place tremendous burden on the patient. We do not feel that any billing system or staff that the vendor would have file their claims will have the knowledge our current offices have. With this in mind, we anticipate that one of two scenarios will occur. First, the vendor just simply bills the patient after the initial claim is submitted and it becomes the patient's responsibility to follow up placing tremendous burden and stress on the patient and their family. The patient would then be required to pay for pharmaceuticals that their insurance should have covered except for the poor billing on the vendor's part. We feel this would be an unfair burden on a severely ill patient. If this situation occurred in the physician's practice, we would work on behalf of the patient to resolve the issue. The second scenario which we see is more likely to occur. ***That is, the vendor will expect the physician to intervene on their behalf and spend staff time to help resolve their payment issues.*** If the physician, already not being reimbursed for additional administrative burdens, does not comply with the vendor's request or if the vendor is not satisfied with the effort, the vendor may use this as a complaint to CMS about the physician. The practice could

be then coerced into handling billing issues on behalf of the vendor, again with no reimbursement for this effort.

⇨ ***Unused Drugs***

Chemotherapy drugs are hazardous materials and require special handling. Within the claim section is reference to the unused drugs. Although not much definition is offered, we would like to raise a few questions in this regard.

When a patient's treatment course is outlined, drugs are ordered from the vendor anticipating that the patient will be able to begin the treatment. In many instances, a patient will present to the office and their examination reveals other problems that would either require a change in their treatment plan or the postponement of the treatment. The proposal suggests that the vendor and physician *"reach an agreement"* on what to do. Any option here contains a *host of possible issues*. For example, if the vendor says to use the drugs for another patient, they would have to make sure that the ID number assigned to the drugs when shipped either is transferred to the other patient or that it is cancelled. ***In either case, that would require the vendor and physician systems be updated in the same manner.***

There are many reasons why drugs would have to be sent back to the vendor other than a change in treatment plan. For example, patients have come in for consultation, education and returned on another day, have the IV started and then decide against chemo therapy. Once the drugs are mixed, they cannot be used in any situation. The vendor cannot bill for drugs not dispensed, the physician followed protocol and the patient exercised their prerogative to forego treatment.

Another scenario to be considered is a patient that moves or transfer care from one physician to another during the course of treatment. One physician has the drugs to send back and the other must order them.

If the drugs are to be sent back to the vendor, who is responsible for that cost? Is it to be assumed that since the physician is returning the product that he/she would bear the cost? *We ask CMS to direct the vendor to outline their position on the return of product.* Many vendors have very definite rules for sending drugs back and these would have to be made known not only to CMS in the selection process but to the physician at the time of his/her consideration of participation.

CMS also needs to consider the cost of hazardous waste material. Currently vials, bags, syringes containing chemotherapy residue are disposed of according to State regulations. ***The vendor would need to be responsible for this process since the reimbursement for administration of the drugs is not sufficient and no additional administrative funds are being made available to the physician.***

Also to be considered is drug waste. ***Since the drugs being delivered to the practice are for specific patients, the use of multi-dose vials will no longer be an option. The use of single dose vials will increase the amount of drug being wasted.*** This will be a tremendous inefficiency and increase the cost rather than decrease the cost of the drug. Any attempt to re-use a vial would either constitute a patient safety issue or be fraudulent billing. Have the pharmaceutical companies been consulted on this issue?

⇨ ***Emergency Situations***

This section also assumes that the physician has an inventory from which to acquire drugs in an emergency situation. The reality is that with the implementation of CAP, a physician may not have an inventory at all. Physician practices rely on volume to help lower the purchase cost of drugs. CAP places all the buying power with the vendor leaving the physician to rely only on that particular source for drugs not only for Medicare patients but all patients treated in the practice. ***To assume that the physician has a personal inventory is an error and should be closely investigated. In addition, the outline of what would constitute an emergency is not adequate.*** This would also place additional burden on the practice should it occur. For example, if the patient does have a supply of a medication on hand and uses some of that stock for a patient, it may be possible for the drug to not be replaced. As stated earlier, in many cases a patient may require a change in medication that is only known when they present for treatment. There would be no way to have this information available prior to their visit and no vendor would be able to get drugs to the physician while the patient waited. The physician would place an order to the vendor indicating that the medication came from personal inventory. The vendor would ship the drug without the patient ID information to replace the drug. The chance of error in this area is great. If the vendor staff did not note that it was replacement drug, the patient has drug shipped that they already had administered. The physician cannot bill for the medication and has paid for the drug. ***We would like CMS to clearly define emergency situations in light of these protocol changes.***

⇨ ***Off Label Use***

Another area that we feel is not solidly defined is the use of FDA approved drugs in off label situations and clinical trials. Oncology treatments are constantly changing and the use of drugs for indications other than the initial release are quite frequent. Currently the Oncologist will work their State Society to gather information supporting the off label use of a product. This information is then sent to our Fiscal Intermediate (WPS for Michigan) and reviewed for approval/denial. The system is very flexible and allows the carrier to review data and make an informed decision. In these situations, the patient's best interest is always of the utmost importance. When the drugs are out of the physician's control, what happens in situations like this? Will the physician be dependent upon the vendor to get approval for off label use? Will the vendor not allow any off label use and restrict the physician's treatment of patients?

Although the drugs in clinical trial are available at no cost, there are ancillary drugs and supplies used in the trial. When a practice enrolls in the trial are the drugs sent to the practice or to the vendor? Who is tracking this part of the inventory? Will the vendor understand the billing nuances for the other medications?

In cases of clinical trials and off label use, the advancement of cancer treatment could be significantly slowed, subject patients to less beneficial treatment but also expose the physician to tremendous liability. ***CMS must firmly outline how off label use of drugs is to be handled and insure that clinical trials are not compromised.***

- **DISPUTE RESOLUTION**

The vendor will be able to report non-conforming physicians to CMS and possibly have the physician removed from the CAP initiative. ***This same prerogative is not offered the physician.***

Once the physician has decided to become a part of CAP, the only indication in the published guidelines for them to change vendors is if the vendor is removed from the program. ***There is no mention of the recourse a practice would have to not only leave the CAP program but to change vendors.*** If a vendor is placing too much burden on the administrative staff in a practice or if they are not adequately working with the patients in the collection of secondary carrier benefits, the physician must continue to order from that vendor for a year even though the relationship is not in anyone's best interest. ***We request CMS to allow physicians the option to change vendors within the year time frame if the initial distributor fails to meet the needs of the practice beyond quality and timely delivery. The way the vendor interacts with the patients should be considered an allowable means of ending the agreement.***

- **CONTRACTING PROCESS-QUALITY AND PRODUCT INTEGRITY ASPECTS**

The MSHO members would like CMS to ***hold the vendors to strict quality control mechanisms.*** This would include requiring vendors to not open or in anyway tamper with the drug containers, carry insurance to cover possible harm caused by their handling of the drugs, include contract language to hold the physician harmless if a lawsuit is initiated because of the possibility of compromised drugs or "gray market" drugs used in treatment and lastly, CMS should audit and enforce the quality standards.

▪ PHYSICIAN ELECTION PROCESS

In order for a physician to make a decision to participate in CAP or not, full and complete information should be made available to them.

This information would include:

- ✓ a complete price list so that they may compare their purchase cost against the amount submitted by the vendor as well as to the reimbursement from CMS on the drugs
- ✓ a detailing of the vendor's drug return policy
- ✓ a detailed explanation of what is expected of them in the submission of orders and ultimately claims
- ✓ claims resolution steps and the burden of the physician
- ✓ the vendor's policy for collecting secondary insurance copays and deductibles
- ✓ a certificate of insurance outlining the liability coverage of the vendor
- ✓ contract language that details the physicians liability
- ✓ a detailed explanation of the vendor's policy regarding direct patient billing
- ✓ certification that prescriptions will be filled according to the physician's orders
- ✓ details of the delivery schedules with an outline of what is to happen if deliveries are delayed for any reason
- ✓ regulations regarding leaving CAP
- ✓ inventory requirements and all the incentives being offered by pharmaceutical companies to the vendor that affects their marketing and product availability.

Based upon the amount of information being gathered and having to be reviewed, we would suggest that the enrollment process be given as much time as possible so that the physician is able to make an informed decision and arrange for the necessary software changes (if any).

As practicing Oncologists the MSHO members can appreciate the efforts of CMS to contain rising costs and not impact the care of cancer patients in the country. We would also like to express our strongest argument against the premise that these changes will not place any additional burden on the physician practice. ***Based upon the outlined needs and the volume of patients treated in Oncology practices, it would not be an exaggeration to state that 1-2 FTE's would be needed per practice to handle the additional duties being imposed. The small and rural practices will be the most severely impacted with these proposed regulations.*** It is not our intention to have to shift patient care to hospitals. Hospitals do not have the infrastructure to handle a large influx of chemo therapy patients. Patients will be required to wait for long periods of time, travel greater distances and loose the comfort of being treated by the same people on an ongoing basis. Our goal to keep the patient in the care of their community oncology practice where the patients come first and the quality of care is well proven and established. However, with the duties and obligations being made upon these practices by CAP, many will not be able to maintain office based treatment.

We also hope that CMS makes decisions with the quality of patient care uppermost in their minds and not just the bottom line.

Thank you for the opportunity for the MSHO membership to expresses their comments and opinions on the proposed regulations.

Thank you for your consideration,

Ernie P. Balcueva, M.D.

Ernie Balcueva, M.D.
President
Michigan Society of Hematology and Oncology

1020 First Avenue
PO Box 61501
King of Prussia, PA 19406-0901
Tel: 610-878-4583
www.zlbbehring.com

APR 25 2005

ZLB Behring

April 22, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

ATTN: CMS-1325-P

Re: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B, Proposed Rule

Dear Dr. McClellan:

ZLB Behring is a leading researcher and manufacturer of life-saving biotherapeutics such as blood clotting factors to treat bleeding disorders, including hemophilia and Von Willebrand disease; intravenous immune globulin (IVIG), for the treatment of immune deficiencies; and alpha$_1$-proteinase inhibitor, used to treat alpha$_1$-antitrypsin deficiency, which is commonly referred to as genetic emphysema. We also expect to launch, subject to regulatory approval, a subcutaneous immune globulin in 2005 for the treatment of primary immune deficiency, including more difficult to treat cases. These therapies are created by pooling and manufacturing donated human blood plasma into lifesaving therapies or by recombinant DNA technology.

Thank you for allowing ZLB Behring the opportunity to comment on the proposed rule regarding implementation of the Competitive Acquisition Program (CAP) for Medicare Part B. Section 1847B of the Social Security Act (the Act), created by the passage of the Medicare Modernization Act (MMA), establishes a CAP for the distribution and reimbursement of Part B covered therapies. ZLB Behring will focus its comments on the section of the proposed rule regarding therapies that should be included or excluded from CAP.

Plasma therapies and their recombinant analogs need to be excluded from CAP to assure patient access to these lifesaving therapies. As patient populations for both bleeding disorders and alpha$_1$-antitrypsin deficiency are very small, with only a segment of those being Medicare eligible, a CAP vendor does not have an incentive, nor is it required, to carry all brands within a class. Further, with such small disease states, it is very unlikely there will be substantial savings under CAP when compared to the Average Sales Price plus 6% model (Section 1847A of the

Act). The Secretary of Health and Human Services should follow the precedent set by Congress within Section 303 (b)(1)(E) of the Act, when it exempted IVIG from the CAP, and exercise his statutory exclusion authority for the remaining plasma-derived therapies and their recombinant analogs.

Our comments will focus on the reasons why blood clotting factor and alpha$_1$-proteinase inhibitor should be excluded from CAP:

1) There are only approximately 1100 people Medicare beneficiaries with hemophilia and 2000 with alpha$_1$-antitrypsin deficiency. CAP savings, if any, will be minimal.

2) Patient access will be significantly affected, as CAP vendors are not required, nor have incentive to carry all NDCs within a HCPCS code for such small populations. The brands are therapeutically different, thus optimal medical treatment requires access to all brands of therapy.

3) The precedent for excluding plasma therapies and their recombinant analogs has been established with the statutory exclusion of IVIG.

4) Congress provided CMS with the statutory authority to exclude therapies from CAP if savings would not be realized or if patient access was affected. CMS is required to consider these criteria.

Categories of Drugs to be Included Under the CAP

Section 1847B (a)(1)(D) of the Act authorizes the Secretary of Health and Human Services to exclude competitively biddable drugs and biologicals from CAP if the application of competitive bidding to such drugs and biologicals is not likely to result in significant savings; or is likely to have an adverse impact on access to such drugs and biologicals. As with IVIG, both of these conditions are met when also considering blood clotting factor, alpha$_1$-proteinase inhibitor and subcutaneous immune globulin.

As such, ZLB Behring is concerned with the statement on page 33 of the proposed rule:

> *"We (CMS) do not propose to rely at this time on the Secretary's authority under section 1847B (a)(1)(D) of the Act to exclude competitively biddable drugs and biologicals from the CAP on the grounds that including those drugs and biologicals would not result in significant savings or would have an adverse impact on access to those drugs and biologicals."*

This statement seems to dismiss any adverse impact on access to drugs or biologicals that may result from CAP. The very reason this section was incorporated into the Act by Congress was to prevent negative impacts on access to therapies, specifically therapies to treat small and chronic patient populations. By rejecting the use of this authority in all circumstances, CMS would be threatening access to and quality of care for certain populations. CMS has the obligation to consider requests for exclusion from the CAP under the criteria of Section 1847B (a)(1)(D) of the Act instead of issuing a blanket rejection of exclusion.

Blood Clotting Factors

Blood clotting factors are used to treat bleeding disorders such as hemophilia and Von Willebrand disease in which an individual is missing a protein essential for the blood to clot. Clotting factor replaces this vital protein and acts to discontinue or prevent bleeding episodes that can be disabling or life threatening.

As with IVIG, there are multiple brands of blood clotting factor within a single hospital common procedure code (HCPC). This is unique among most drug and biological HCPC codes but is common for HCPC codes regarding plasma-derived therapies and their recombinant analogs. A primary reason IVIG was exempted from CAP was that multiple brands within the single HCPC code (J 1563) have differing treatment characteristics. This is also common for blood clotting factors as individual patients may respond differently to each of the brands within the HCPC code. Therefore, physicians and patients require access to the range of therapies in order to assure appropriate treatment.

CAP would not guarantee access to each brand of therapy within a HCPC code, thus patient care could suffer. Specifically, page 32 of the proposed rule states:

> *"As discussed in (regulation) proposed §414.908(d), we are proposing that vendors will not be required to provide every National Drug Code associated with a HCPC code"*

With this provision CMS is projecting that brands of blood clotting factor are interchangeable when in fact they are not. As an example, recombinant factor VIII (J 7192) has five brands used in the treatment of hemophilia A. However, the brands are not all of the same composition and individuals react differently to the specific brands. One brand may have a greater possibility than another for the development of an inhibitor, in which the infused protein is viewed as a foreign entity and attacked by the individual's immune system. A patient can develop an allergic reaction to one particular brand and not another due to the varying formulations. Prophylaxis treatment protocols for brands differ and, in some instances, an individual with hemophilia may not achieve

hemostasis as quickly, or at all, by using a particular brand of recombinant factor VIII. Similar issues also apply for other classes of blood clotting factors including, but not limited to anti-hemophilic factor VIII (J 7190); anti-hemophilic factor IX, purified (J 7193); anti-hemophilic factor IX, complex (J 7194); and Von Willebrand Factor Complex (Q 2022).

The Government Accountability Office, when determining an appropriate add-on payment for blood clotting factor under section 1847A of the Act, determined that only 1100 people with hemophilia (out of 17000 in the US) have Medicare as their primary insurer. As the CAP reimbursement rate will be the average of all accepted bids, and the regional CAP vendors will not obtain volume discounts in purchasing as they might with oncology and urology therapies, it is not likely that reimbursement under CAP will be significantly lower than ASP plus 6%. As we are speaking of only 1100 people, the savings, if any, would be small.

The proposed rule and the MMA contain conflicting statements regarding therapies such as blood clotting factors that need clarification. There are those who interpret the statutory definition of "competitively biddable drugs" to exclude blood clotting factor because in most cases it is not administered incident to a physician's service, it is not administered through a DME, and it is usually not dispensed by a regular pharmacy. Additionally, page 22 of the proposed rule regarding therapies not included within CAP states:

> *"Medicare Part B covered vaccines, drugs infused through a covered item of DME, and blood and blood products (not including clotting factor and intravenous immune globulin (IVIG)) are not included in the CAP because they are expressly excluded from section 1842 (o)(1)(c) of the Act."*

Section 303 (b)(1)(F) of the MMA states:

> *"In the case of blood and blood products (other than blood clotting factors), the amount of payment shall be determined in the same manner as such amount of payment was determined on October 1, 2003."*

This section indicates that blood and blood products other than blood clotting factor are exempt from CAP. Yet the above citation from page 22 of the proposed rule links blood clotting factor and IVIG. As IVIG is excluded, is CMS stating that blood clotting factors are also excluded from CAP? Clarification regarding the status of blood clotting factors under CAP is requested so that this important topic can be completely understood.

Alpha$_1$-Proteinase Inhibitor

Weekly infusions of alpha$_1$-proteinase inhibitor help maintain a protective level of alpha$_1$ protein in the blood stream. Without adequate therapy, patients suffer from repeated infections resulting in reduced lung function, hospitalization and reduced quality of life. Others develop relentless, progressive pulmonary emphysema, often leading to premature death. Access to this life-saving therapy is critical in maintaining lung function, thus life itself.

As with blood clotting factors and IVIG, there are multiple products within the HCPC code for alpha$_1$-proteinase inhibitor (J 0256). At present, there are three brands of therapy that are included within J 0256, two of which have recently been introduced to the market and one that has been available for approximately 15 years. ZLB Behring is concerned that a regional vendor would only supply the single, older therapy and neither of the two newer therapies that represent different treatment options for alpha$_1$-antitrypsin deficiency.

According to the Alpha-1 Foundation, approximately 5000 individuals in the United States have been diagnosed with alpha$_1$-antitrypsin deficiency, of which approximately 40% are Medicare beneficiaries. With such a limited number of beneficiaries, CAP would not result in substantial savings compared to ASP plus 6%. Further, the CAP vendor may not have the financial ability and desire to provide access to all brands for such a small population. The Secretary of HHS should use his exclusion authority to exempt alpha$_1$-proteinase inhibitor from CAP for both the lack of savings and the negative impact on access that would occur.

Subcutaneous Immune Globulin

As previously indicated, ZLB Behring plans to introduce a subcutaneous immune globulin to the United States market in the latter half of 2005. We believe this therapy will be an innovative step in the advancement of immune globulin for treating individuals with primary immune deficiency, including treatment of patients who have difficulty tolerating intravenous traditional methods of administering immune globulin. ZLB Behring seeks confirmation that the CAP exclusion for IVIG would also apply to this version of immune globulin that will be used to treat many from the same primary immune deficient population. ZLB Behring believes that in excluding IVIG from CAP, Congress intended to ensure access to immune globulin therapy for conditions like primary immune deficiency and not solely the intravenous delivery method currently utilized. To exempt IVIG but not the subcutaneous therapy would disadvantage access to a new approach in treatment that could benefit segments of the immune deficient population. Therefore we request that CMS explicitly exempt subcutaneous immune globulin from CAP implementation.

Conclusion

Congress saw the need to exempt IVIG from CAP, given the need for patients and physicians to have available the multiple brands of therapy contained within an individual HCPC code and the belief that contracted vendors would not be able to assure access given the small patient population. The same rationale holds true for blood clotting factors and alpha$_1$-proteinase inhibitor. Both types of therapy have multiple brands within a HCPC code, both are derived from human blood plasma or a recombinant analog, and both therapies have multiple brands within a HCPC code that are not interchangeable. In fact, it is our understanding that members of Congress have expressed to CMS their concerns and desire to have these therapies exempted from the CAP through the use of the Secretary's exclusion authority. Unlike therapies with wider utilization such as oncology and urology, each plasma or recombinant analog therapy is utilized in such a small scope that savings under CAP cannot be assumed when compared to ASP plus 6%. And, no single vendor is likely to stock all brands of therapies, even if they so desired, for these rare conditions given the very small populations in each likely competitive bidding geographic area. The probable scenario would be a bidder limiting access to much less than the full range available within a HCPCS code. A number of treatment providers still would rely on that system rather than seek to administer the products under the ASP alternative. Alternative providers stocking more brands also would be less available once a bid is awarded to vendors given the small populations.

ZLB Behring requests that blood clotting factors, alpha$_1$-proteinase inhibitor and subcutaneous immune globulin be treated in a similar manner as IVIG and exempted from CAP. It is our hope that the Secretary of HHS will use his exclusion authority, thus ensuring that patients with these rare conditions will continue to have access to all life-saving brands of plasma and recombinant analog therapies.

As you likely are aware, the Immune Deficiency Foundation reports that changes in reimbursement enacted in part B for IVIG under the MMA have resulted in some physicians no longer administering IVIG, or the desired brand. Individuals at CMS now are trying to explore ways to restore access. Access to clotting factor experienced strong challenges under part B after reimbursement transitioned to ASP plus, and CMS agreed to increase the add-on payments after considerable patient anxiety and problems with access. There has been substantial industry consolidation given the challenges in producing these complex biotherapies for small populations and long-term access to brands has to be considered. These instances, and others in history, demonstrate that delivery of therapy to these small populations really is a delicate balance that does not lend itself to approaches possibly suitable for broadly distributed products. The best way to avoid having to make a fix after CAP is implemented is to learn

ZLB Behring

from these lessons and the reality of these markets, and exempt the abovementioned plasma therapeutics from CAP when the final rule is issued.

We would be very happy to meet in person or by teleconference to discuss in more detail. Should there be any questions or if we may be of assistance, please feel free to contact me or Patrick Collins (610-878-4311). Your consideration of our comments is greatly appreciated.

Sincerely,

Dennis Jackman
Senior Vice President, Public Affairs

Oncology Care Associates, P.A.

Carolyn B. Hendricks, M.D.
Oncology

Cheryl A. Aylesworth, M.D.
Hematology / Oncology

April 21, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS – 1325
PO Box 8010
Baltimore, MD 21244-8010

RE: File Code CMS – 1325-P

Dear Sir or Madam,

I am a medical oncologist in private practice in Montgomery County, MD. My practice is composed of three full time medical oncologists, an oncology nurse practitioner and five oncology nurses. I am submitting the following comments on the proposed rule implementing the Medicare Competitive Acquisition Program (CAP).

Comments on Overview of the CAP: Although Congress has decreed that CAP should be effective on January 1, 2006, I strongly urge CMS to take the time it needs to fully understand how CAP can best be structured to attain Congress' objectives and benefit physicians like us without compromising access to drug therapies and treatment. To ensure an effective launch with adequate physician participation by practices like mine, CMS should delay the effective date of CAP.

Comments on Categories of Drugs to be included under CAP: Once CMS has decided what phase-in approach it will take for CAP, a section notice should be published in the Federal Register to allow for additional public comment such as this before the proposal is adopted as a final rule. The final rule must make clear that formularies are not permitted. The final rule should provide that during the annual election period and upon request a CAP vendor must fully disclose each drug that the vendor will make available pursuant to its CAP contract. Vendors must be prohibited from making any changes in the list of drugs available through CAP within 90 days of the annual election period or after the expiration of 90 days following the election period without 90 days advance written notice to all participating physicians. We should have the right to opt out of CAP if a vendor fails to make proper disclosures or fails to make drugs available that we determine are medically necessary for the treatment of our patients. CMS needs to identify a methodology for monitoring how CAP impacts medical oncology practices such as mine, including the access to treatment for our patients and the impact on our costs.

6410 Rockledge Drive, Ste. 625 • Bethesda, Maryland 20817
Phone: 301-897-1503 • Fax: 301-581-0254

Comments on Competitive Acquisition Areas: Once CMS has decided how to define a "competitive acquisition area," a second notice should be published in the Federal Register before the proposal can be adopted as a final rule.

Comments on Statutory Requirements Concerning Claims Processing: CMS should restructure CAPS' proposed claims process and tracking requirements to reduce my administrative burdens. Vendors should be prohibited from splitting shipments unless we approve. We should be permitted to resupply our inventories if the drugs are required immediately, if we could not have anticipated the need for the drugs, if the vendor cannot deliver the drugs in a timely manner, and/or the drugs are required in an emergency situation. CMS should recognize and compensate us for the costs of drug handling and delivery. CMS needs to clarify the language related to the requirement for written prescriptions (as opposed to orders) for drugs and insure that "furnish as written" orders are reviewed under the same standards and process used under Medicare Part B for non-CAP drug acquisitions. We should be given a choice of which categories of drugs to obtain from a particular CAP vendor. The final rule must make clear that vendors cannot refuse to deliver drugs because they are unable to collect co-payments. Alternatively, if CMS does allow vendors to stop delivering drugs, this must be made very clear to us during the CAP election period that the vendor may suspend treatment to any patient not paying their co-insurance. Additionally, we must be permitted to immediately opt out of CAP and obtain drugs through the ASP system in any case where a vendor has decided not to ship drugs for a patient not paying the Medicare co-insurance.

Comments on Contracting Process Quality and Product Integrity Aspects: CMS must strengthen the rules pertaining to quality and performance standards of vendors and clarify the procedures that will be used to investigate allegations involving the poor performance of vendors. Vendors who fail to perform should be subject to investigation and sanction, up to and including exclusion from the program. CMS should develop standard "hold harmless" language for the CAP election agreement that ensures that participating physicians are held harmless for the negligence and non-performance of CAP vendors. CMS must make it clear that we can disenroll from CAP at any time, especially in cases of quality non-performance.

Comments on Bidding Entry Qualifications: A CAP vendor should be required to demonstrate a history of at least 3 years of delivering each category of drugs for which they submit a bid. Vendors should be required to have the capacity to make same day deliveries when drugs are needed on an emergency basis. At the time the drug is ordered, we should receive a commitment from the CAP vendor for a day and time of delivery, and vendors must be held accountable for compliance that that commitment. Formularies should not be allowed.

Comments on CAP Bidding Process – Evaluation and Selection: CMS must revise the bid process to avoid a situation where drug price considerations become more important than quality and efficacy. We need the ability to walk away from the system to help keep vendors sensitive and responsive to quality concerns. CMS must adjust out payments for services to more accurately reflect our costs.

Comments on Physician Election Process: CMS must make clear that we can disenroll from CAP at any time.

Comments on Beneficiary Education: CMS should conduct outreach and beneficiary education to patients receiving treatment under Medicare Part B. CMS should revise its estimate to reflect the additional time it will take to evaluate CAP. CMS must fully analyze the application requirements and administrative costs by conducting a test with community oncology practices such as ours and reporting back on the results. CMS should do a complete impact analysis that both examines and quantifies the true cost of CAP to our practice and quantifies the overall impact of CAP on the delivery of cancer care in this country.

In summary, there are ten serious problems with CAP which will impact my practice.

- Our practice will be locked into a CAP vendor for one year.
- CAP vendors will be able to establish formularies based on price.
- Our practice will need to maintain individual drug inventories with the potential for waste from unused and unusable medications.
- We will be unable to resupply our own inventories unless multiple conditions are met. If patient's needs (as they frequently do), their chemotherapy appointments will need to be rescheduled.
- There are no provisions for emergency delivery of drugs.
- Our claims processing burden will increase.
- Vendors may have community oncologists investigated and excluded.
- Drug treatment splitting would be permitted without our authorization.
- Even if there are concerns about quality and service from a vendor, we will still be locked in a one-year CAP election.
- Our pharmacy costs will remain unreimbursed.

I am seriously concerned about CMS's approach and the program's proposed structure and options that may render this program unworkable for my oncology practice.

Sincerely,

Carolyn B. Hendricks, MD
President, Oncology Care Associates, PA

Community Support Services, Inc.

Quality Behavioral Healthcare

APR 25 2005

MAIN OFFICE
150 Cross Street
Akron, Ohio 44311

Administration
(330) 996-9141
Fax: (330) 253-0377
www.cssbh.org

Case Management
Psychiatric Services
(330) 253-9388
Fax: (330) 376-6726
Northern Summit County
(800) 268-0014

SERVICE LOCATIONS
640 Wolf Ledges Parkway
Akron, Ohio 44311

Clean Sweep - Vocational
Work Tech - Employment
Intensive Treatment Services
Residential Administration
(330) 253-9675
Fax: (330) 996-9146

Homeless Outreach
(330) 762-4663
Fax: (330) 996-9146

Summit County Jail
Behavioral Health Services
205 E. Crosier Street
Akron, Ohio 44311
(330) 643-2145
Fax: (330) 643-5414

Edgerton House
117 Edgerton Road
Akron, Ohio 44303
(330) 836-6687
Fax: (330) 836-4282

Kibler Hall
101 Ambassador Drive
Akron, Ohio 44312
(330) 733-6203
Fax: (330) 733-5045

Maggie Carroll Smith House
1770 2nd Street
Cuyahoga Falls, Ohio 44221
(330) 923-9957
Fax: (330) 923-9965

April 20, 2005

Centers for Medicaid and Medicare Services
Department of Health and Human Services
Attention: CMS-1325P
P.O. Box 8010
Baltimore, MD 21244-8010

To Whom It May Concern:

On behalf of Community Support Services, Inc., a large behavioral health services organization serving approximately 2600 individuals with severe and persistent mental illnesses, I would like to provide some comment regarding the Competitive Acquisition Program (CAP). Although CSS strongly supports the implementation of CAP, we encourage you to include psychiatric drugs, including long-acting injectable anti-psychotics, in Phase I.

Behavioral healthcare organizations, for the most part, are not-for-profit 501(c)3 organizations. With the development of new generation psychiatric medications, including long-acting injectable anti-psychotic medications, behavioral healthcare organizations have, out of necessity, been required to increase administrative overhead costs to implement some of these new programs/medications. Including psychiatric medications within the CAP would allow agencies to put their limited financial resources into client care rather than administrative overhead.

Many of the 2600 individuals served by CSS have severe cognitive impairments. A significant number of these individuals are either Medicare eligible or are "dual eligibles." Any process that would simplify the process to ensure timely and dependable acquisition of required medications would be extremely important to those receiving care as well as those providing the care.

I also would like to encourage CMS to ensure the formularies be inclusive of most of the new generation medications which have

permitted individuals, who had previously been marginalized within our society, to become productive employed tax paying citizens. Failure to provide an inclusive formulary of psychiatric medications will result in numerous client failures and an increased burden on family, care providers and society as a whole.

I encourage you to keep a positive process moving forward.

Sincerely,

Terrence B. Dalton
Chief Operating Officer

TBD/jj

5b

NAMI Fort Wayne
P.O. Box 6143
Fort Wayne, IN 46896-0143
Phone: 260-447-8990

April 19, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1325-P
PO Box 8010
Baltimore, MD 21244-8010

RE: CAP inclusion of psychiatric drugs

To Whom It May Concern:

NAMI Fort Wayne is a grassroots, nonprofit organization dedicated to improving the lives of people with serious mental illnesses. We have provided support, education and advocacy to consumers and their families for 25 years, and have over 350 members in our local affiliate.

NAMI knows treatment works, but access to appropriate and effective treatment is sometimes a challenge. Even though Indiana was the 13th state to pass parity, private insurance companies continue to restrict the number of visits to psychiatrists and therapists, and access to certain medications. Formularies are designed with fail-first medication options as a means to reduce costs by requiring physicians to prescribe generics.

Many patients on Medicaid and Medicare rely on community mental health centers (CMHC), such as Park Center in Fort Wayne, for all of their mental health services, including medications. Some patients use injectable medications such as Haldol, Risperdal Consta, or Prolixen. For these patients, this is the only way they can receive their medications and get relief from their symptoms. Without access to these medications, some patients will relapse, requiring more intensive and expensive services.

Under the current "buy and bill" system, some physicians and CMHCs cannot afford the overhead and administration expenses inherent in providing non-self administered psychiatric medications. Their patients are simply not offered these medications. For many individuals, whether in the private or public health care system, the right medications have awakened them from the haze of psychosis and allowed them to return to a full and productive life. To simply not provide that possibility is inhumane!

- NAMI urges CMS to include psychiatric drugs in the Competitive Acquisition Program (CAP), and to begin immediately with the Phase I to alleviate existing barriers to access.
- NAMI encourages CMS to create a category of Part B that includes mental health drugs, such as injectable Haldol, Prolixen, or Risperdal Consta.

- NAMI also recommends that CMS address how vendors should handle uncollectible copays to ensure individuals receive the medications they so desperately need and are not denied based on inability to pay.

Please join us in helping people with mental illnesses receive the most appropriate medications for their individual needs, by including psychiatric medications in the proposed CAP program.

Sincerely,

Nancy J. Bean
Director of Education
NAMI Fort Wayne

52

NEW MEXICO ONCOLOGY HEMATOLOGY CONSULTANTS, LTD. AT NEW MEXICO CANCER CENTER

4901 LANG AVE. NE. ALBUQUERQUE, N.M. 87109-4397 TELE: 505.842.8171

April 20, 2005

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325P
PO Box 8010
Baltimore, MD 21244-8010

Re: Comments on the Proposal for Competitive Acquisition of Outpatient Drugs and Biologicals under Medicare Part B

Drugs to be included in the CAP:

Currently because of the ASP Plus 6% pricing, many drugs are unavailable to physicians to purchase for the Medicare payment amount. Therefore, if a CAP program is to have any value it would have to be all chemotherapy drugs. It would be impossible to put in a limited specific formulary as all chemotherapy drugs have specific indications and are used.

Plan Processing Overview:

I am very concerned about the claims processing part. Our carrier is used to receiving an administration claim at the same time as a drug claim. The increased administrative expense of making sure that the prescription number was correctly submitted and carried on when a claim is denied or delayed will be a major impediment to our use of the CAP and will increase our administrative overhead.

It must be an absolute requirement for vendors to fill all orders. It is absolutely imperative that a vendor must fill all physician orders despite a temptation to refuse filling them for a patient who has not paid their co-insurance amount or when an ongoing appeal of coverage denials is occurring. Cancer patients must not have their care interrupted for financial means.

CLARK E. HASKINS, M.D., DIPLOMATE, MEDICAL ONCOLOGY
BARBARA L. MCANENY, M.D., DIPLOMATE, MEDICAL ONCOLOGY; DIPLOMATE, MEDICAL HEMATOLOGY
RICHARD O. GIUDICE, M.D., DIPLOMATE, MEDICAL ONCOLOGY; DIPLOMATE, MEDICAL HEMATOLOGY
JAMES E. LIEBMANN, M.D., DIPLOMATE, MEDICAL ONCOLOGY
DOUGLAS A. CLARK, M.D., DIPLOMATE, MEDICAL ONCOLOGY; DIPLOMATE, MEDICAL HEMATOLOGY
NATALIE A. MARSHALL, M.D., DIPLOMATE, MEDICAL ONCOLOGY
JAN M. MERIN, M.D., M.P.H., DIPLOMATE, MEDICAL ONCOLOGY

STEVEN E. BUSH, M.D., DIPLOMATE, RADIATION ONCOLOGY
JOEL H. ELCONIN, M.D., DIPLOMATE, RADIATION ONCOLOGY
BRYAN W. GOSS, M.D., DIPLOMATE, RADIATION ONCOLOGY

Information to be submitted with the order:

Your proposed regulation requires us to submit frequency and instructions, anticipated date of drug administrations, information about the patient's secondary insurance and additional patient information such as date of birth, allergies, height, weight, etc., to the vendor. I think the last additional patient information is entirely inappropriate. I expect it would be of value to the CAP vendors when they try to sell their information to pharmaceutical manufacturers, but I do not believe that as a physician I wish to contribute to that endeavor. It will also be impossible to describe the frequency and instructions because cancer care is often a very patient-specific event and modifications are frequent. If one submitted a frequency that changed, the additional difficulty in getting the order properly resubmitted might be extensive and very expensive for the practice to administer.

I agree with the fact that all drugs must be delivered to the physician's office. However, because we have multiple locations, I feel it is important to make sure that the drug is delivered to the proper location. Physician practices will not be able to afford transporting drugs from one location to another. Similarly, we cannot afford the cost of transporting damaged goods or drugs we feel have been improperly handled back to the vendor. This cost should be incurred by the vendors, not by the physician practice. In all inventory situations some shrinkage is inevitable. In oncology practices, this occurs by accidental breakage of the vial or receiving a vial of cloudy solution. Physician practices must not carry the cost of this inventory inevitability.

The physician practice also needs to be assured that if the infusion is started and the patient has a reaction and cannot receive the first chemotherapy drug or any of the subsequent ones that were scheduled on that day, the physician or the patient will not be penalized by having to pay for the cost of those drugs. That cost should be borne by the vendor or by CMS.

Time for submission of claims:

We try very hard to submit all claims for drug administrations within 14 days. However, that is often not practical and we are not able to achieve that goal in the office. We therefore would request that you give us at least 30 days to submit a claim.

Disposition of unused drugs:

The cost of disposing of unused drugs should be borne by the vendor, not by the physician. Because chemotherapy patients sometimes have infections or other intercurrent illnesses which cause delays in the planned schedule of their chemotherapy, the physician should not be penalized and the vendor should not assume that the drug will therefore be unused. It will be very difficult for the physician to develop an inventory management system to track the use of the drugs. The additional overhead to do so would be prohibitive for the delivery of chemotherapy.

Physician practices should not also be forced to pay the shipping costs and the storage costs of taking care of unused drugs or returning drugs to the vendor.

Payment for administrative costs:

CMS makes the assumption that it will not cost any more for physician to obtain drugs through a CAP vendor versus having inventory on site. I strongly disagree with that assumption. I can buy drugs in bulk and keep a stock based on my usual use. This has a much smaller inventory cost than obtaining patient-specific drugs and keeping track of which patient's drug goes with which prescription number. The administrative work that oncologists have discussed with me in systems which have allowed brown bagging was considerable. I do not wish to hire additional personnel and systems to try to keep track of drugs obtained through a CAP vendor but to comply with CMS regulations, additional personnel would be necessary. I would also be forced to keep a separate inventory for my non-Medicare patients separately from my cap Medicare patients so that I can keep track of whether or not I have enough for the non-Medicare patients. I am also very concerned that vendors may require specific computerized systems and require acquisition of their specific technology at our cost.

Dispute resolution:

With the interposition of CAP vendors between the physician and the patient, I think it is crucial that the process be made clear to beneficiaries. Let patients know that the vendors will be billing them for this and that I, as a physician, will have no ability to intervene between them and the vendor. I do not want to be vilified when vendors attempt to not provide drugs to patients who are unable to make their co-pays.

Quality and Product Integrity:

I would refuse on a patient safety basis to ever deliver a medication which had been premixed. The containers would have to be supplied to me in their original form and if the drug were opened or if I had any suspicion it had been tampered with, I would need the ability to return it to the vendor without penalty and without cost. I am also very concerned about the increased liability that I will have by any drug reactions which can occur on a drug handled by a vendor.

Holding entry qualifications:

I do not wish to provide patient and physician specific data about drug therapies to vendors. Whether or not that violates HIPAA, I feel that it is an invasion of patient privacy and practice privacy to allow vendors to use our data for their own financial gain. I also feel very strongly that vendors may not be allowed to market to patients. If a vendor decides that they wish to market an alternative regimen on the basis that it is cheaper, that is an unconscionable intrusion into the physician-patient relationship. There are likely other reasons why a specific regimen is chosen other than cost that the vendor would not have access to.

As soon as a drug is FDA approved it should be available from the CAP immediately.

Physician election process:

Living in a small state with a low population and limited resources, I am very concerned that there may not be more than one CAP vendor in our area. If a CAP vendor becomes unacceptable, I should have the option to opt out earlier than one year. If the CAP vendor leaves the program in midyear, I do not know what my options would be under your proposed rule.

Beneficiary education:

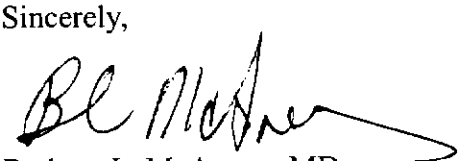
I am very concerned that patients will not understand the entry of a CAP vendor into their current relationship with physicians. I do not want any part of preparing the fact sheet on the CAP program or making it available to my patients. I feel that it is the job of CMS and of the vendor to explain to patients why they are receiving multiple bills and co-insurance bills from people they have never heard of. The explanation of this program would be very time consuming and is an expensive unfunded mandate on physicians.

CMS monitoring of programs:

I am very concerned that the interposition of the cap vendor program will limit Medicare patients' access to drugs given incident to physician services. In rural areas where one or two doctor practices predominate, physicians may discover that the inadequacy of administration payments, and the increasing costs of meeting CMS, OSHA and other regulations may make it impossible for them to provide the infrastructure that allows the safe delivery of chemotherapy medications. Physicians already facing decreased reimbursements may find that the required facility and nursing overhead are beyond their means when they would only be paid for by the non-Medicare population. A hood, the OSHA inspections and requirements which attend it, the mixing room, the storage of chemotherapy medication is all expensive and is not currently covered in the administration fees. Oncology nurses are hard to find and expensive to keep. If there are no drug margins and increasing overhead costs, many physician practices may decide that the administration of chemotherapy to their patients is no longer cost-effective for either Medicare or non-Medicare patients. This may cause specific physician practices to discontinue these services and in rural areas the hospitals cannot pick up the slack. There are no other close options for patients in rural areas. Rural patients will have to travel hundreds of miles to the next closest chemotherapy infusion center or forego treatment. I believe that it is the duty of CMS to monitor this program to make sure that rural seniors are not disadvantaged in cancer care.

Thank you very much for listening to my comments.

Sincerely,



Barbara L. McAneny, MD
CEO, New Mexico Cancer Center

BLM/tw

ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

APR 25

April 21, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Comments on the Proposal for Competitive Acquisition of Outpatient Drugs and Biologicals Under Medicare Part B

These comments are submitted by the American Society of Clinical Oncology (ASCO) in response to the proposed rules governing the Competitive Acquisition Program (CAP) for drugs administered in physician offices, which were published in the Federal Register on March 4, 2005. ASCO is the national organization representing physicians who specialize in the treatment of cancer. Drugs used in cancer chemotherapy represent a substantial portion of the drugs covered by Medicare Part B, and ASCO's members therefore are very interested in the design and implementation of the CAP.

ASCO has a number of concerns with the proposed regulations. As requested in the Federal Register notice, our comments are organized by the subjects specified in the notice.

DRUGS TO BE INCLUDED IN THE CAP

The statute allows CMS to phase in the CAP, and CMS has asked for comments on various possibilities. In terms of the drugs covered by the CAP, one approach would be to start with the relatively large number of drugs typically used by oncologists, a second approach would be to start with a smaller number of drugs used by other specialties, and a third approach would be to include all drugs in the CAP. In terms of geography, the CAP could initially begin nationwide or, alternatively, only in certain regions.

Implementation of the CAP

As outlined in these comments, ASCO believes that there are a number of issues that require clarification to ensure that the CAP will operate appropriately. We are uncertain whether the CAP will be widely accepted by oncologists because of

these uncertainties and the additional administrative burdens that the program will impose. Nevertheless, ASCO urges that the CAP be made available nationwide in 2006 for all drugs.

The current reimbursement system, which sets payment at 106% of a historical average sales price, results in some drugs being unavailable to some physicians at a price that is less than the Medicare payment amount. Physicians should have the opportunity to avoid these out-of-pocket losses, as well as other drug-associated losses such as bad debt, by electing to participate in the CAP. During the legislative consideration of the Medicare Modernization Act, the CAP was portrayed as an option that would be available to physicians who would otherwise incur losses. This protection should be offered to physicians who want it without delay beyond 2006.

CLAIMS PROCESSING OVERVIEW

As described in the proposal, in response to orders from physicians with respect to specific patients, the vendor would send the drugs to the physician with an identifying prescription number. When the physician administers a drug, he would submit a claim to his local carrier showing the drug administration codes, the J-codes for the drugs administered, and the prescription number supplied by the vendor for the drugs administered.

The local carrier would adjudicate the claim as usual and would determine whether it was a Medicare-covered service, applying local coverage determinations as applicable. If the service was covered, the local carrier would notify the carrier that handles vendor drug claims of the prescription number involved, at which time the drug carrier would pay the vendor and the vendor would be permitted to bill the patient, or the patient's secondary insurer, for the coinsurance.

Requirement for vendor to fill all orders

It is implicit in the proposed regulations that a vendor must fill all physician orders, but this should be made explicit. Vendors may be tempted to refuse filling a particular order for various reasons – e.g., the patient involved has not paid coinsurance owed to the vendor for a previous order, the Medicare carrier has denied coverage of a similar previous order, the vendor thinks that the carrier might deny coverage, etc. The regulations should state unequivocally that the vendor may not refuse to fill a properly completed physician's order for any reason whatever. Similarly, the regulations should provide that the vendor cannot require the patient to sign an advance beneficiary notice, in which the patient agrees to pay for the drug in the event of a coverage denial.

Information to be submitted with the order

The proposal would require the physician, in ordering a drug, to specify the "frequency/instructions," the anticipated date of drug administration, information about the patient's secondary insurance, and "additional patient info: date of birth, allergies, Ht/Wt/ICD-9, etc." Information on secondary insurance is appropriate because the vendor will need that information in billing for the coinsurance, but much of the other information would not appear to be relevant to the vendor's duties, and there should not be a requirement for its submission.

Specifically, information on "frequency/instructions," date of birth, allergies, height, weight, and diagnosis code seems to contemplate that the vendor will perform a pharmacist-type review of the order and label the drugs with instructions for use. We do not see any basis in the law for such action. We believe that the statute intends that the vendor act like a drug wholesaler does now, simply filling orders.

Delivery of drugs to office

CMS is proposing that all drugs will be delivered to the physician's office and not the patient. ASCO agrees with this proposal. To ensure proper handling, drugs should be delivered only to physicians.

Practices with multiple locations

Many practices have more than one office location. CMS should require the vendors to deliver each order to the office specified by the practice and not permit vendors to require that practices designate a single address for shipments.

Time for submission of claims

CMS is proposing that the physician would be required to submit all claims for drug administration services with fourteen days of the date of service. While we understand the need for prompt submission of claims, since the vendor is not paid for the drug until the drug has been administered, that schedule is too rapid for many practices. ASCO recommends instead that drug administration claims be required to be submitted within 30 days after the date of service.

Disposition of unused drug

The proposal contemplates that the physician, in ordering drugs for a particular patient, will specify an expected date of administration. If the drug supplied by a vendor is not administered on that date, the physician would notify the vendor and "reach an agreement on how to handle the unused drug, consistent with applicable State and Federal Law." If the vendor and the physician agree that the drug could be used at a later time for another Medicare patient, the

physician would generate a new order for that other patient but note on the form that the vendor need not ship the drug. We have several issues with this aspect of the proposal.

First, the proposal appears to contemplate that the physician can predict the exact date on which drugs will be administered to the patient. A patient's schedule for cancer chemotherapy is subject to change based on the patient's condition, and it should not be assumed, as the proposal does, that a failure to administer a particular drug on the date predicted in advance means that the drug will go unused.

Second, it would be much more practical for the vendor to track the use of drug than the physician. The proposal contemplates that physicians would develop a new system of inventory records for each drug. An additional requirement that each drug must be tracked against the expected administration date provided to the vendor would be another system that would need to be developed and would be quite burdensome. We suggest that the vendor track the expected administration dates against claims submission, and if there is a substantial discrepancy (e.g., no claim submission within a reasonable time after the expected administration date), the vendor would query the physician about the status of the drug.

Third, the process for disposing of unused drug should be clarified. The proposal implies that the disposition of unused drug is at the discretion of the vendor and that, if the vendor cannot develop a solution that is consistent with the state and federal law, the vendor incurs the financial loss. While we understand that CMS cannot resolve all of the state law questions that may be involved, it would be useful if CMS clarified the principles involved. In particular:

- Is the vendor allowed to do anything with the unused drug that is permissible under state law or are there any restrictions under the CAP or other federal law that would apply?

- To what extent is the physician required to cooperate with the vendor with respect to unused drug? For example, if the vendor concludes that it can legally take the unused drug back from the physician, is the physician required to send the drug back? If so, the physician should be permitted to charge the vendor a fee for the service of returning the drug; is such a charge allowed?

- Is the physician required to mitigate the vendor's loss by offering to administer the drug to a different Medicare patient?

- If it is permissible under state law, can the physician negotiate with the vendor to purchase the drug from the vendor at an agreed-upon price?

Payment for administrative costs

CMS is proposing not to make any payment to physicians for the administrative costs associated with obtaining drugs through the CAP on the ground that the inventory and clerical costs do not exceed those that are incurred by physicians who buy drugs and seek reimbursement. ASCO disagrees with this conclusion and requests that a separate payment be established. As we will now outline, at each step in the process of procuring, using, and billing for drugs under the CAP, the administrative work is greater than under the reimbursement system.

The costs of ordering drugs under the CAP would be significantly greater than under the reimbursement system. Under the reimbursement system, physicians generally maintain an inventory for each type of drug and order additional units when the inventory falls below a certain level. Oncologists often use an automated storage and inventory control system that tracks the remaining amount of each drug. By contrast to this relatively simple method of ordering in bulk, the CAP requires orders to be submitted to the vendor for each patient, and those orders would need to provide significant patient-specific information instead of simply the number of units requested.

An additional significant new cost would be the creation of an inventory record for each drug, as the proposal would require. The identity of each drug received from the CAP vendor would need to be entered into a record together with the identifying number furnished by the CAP, and a further entry into the inventory record would be required when the drug was administered. Physicians currently do not maintain any similar inventory records, and the additional work involved would appear to be substantial.

The storage costs would be at least as large under the CAP as under the reimbursement method, and storage may be more difficult to manage. Although the proposal states that the CAP drug inventory would not need to be segregated from other inventory, there may need to be some form of segregation so that the office staff can ascertain the amount of inventory available for non-Medicare patients. For example, if a physician has ten vials of a particular drug on hand, it will not be clear from visual observation whether all of the vials have been received from the vendor for Medicare patients or whether part of the inventory is available for non-Medicare patients.

At the billing stage, there would be more work under the CAP than under the reimbursement method. The content of the claims would be identical in most respects under both systems, but the CAP claim would need to include a prescription number for each of the drug codes billed. Retrieving the prescription number for each drug and including it in the claim would be significant additional work beyond what is now required.

CMS has proposed that if the drug is not used on what was reported to the vendor as the expected date of administration, the physician would be required to notify the vendor. ASCO

has recommended in these comments that physicians should be relieved of that duty, but as proposed, this would be a new reporting obligation that is not comparable to any work in the reimbursement system.

In sum, ASCO does not see the basis for CMS's conclusion that no extra administrative costs are incurred by physicians participating in the CAP. To the contrary, there would appear to be significant additional work involved. We recommend that a reasonable payment be established that would fully cover the extra costs involved. The payment amount could be paid with respect to each drug administered. That is, the claim submitted to Medicare for an encounter involving drug administration would include a code for the drug handling service with the units reported for the code equal to the number of drugs administered during the encounter.

Vendor-imposed technology costs

If a vendor imposes any requirements that physicians use particular hardware or software in submitting orders or otherwise participating in the CAP, CMS should require the vendor to clearly disclose those requirements prior to the election period. If physicians are responsible for the costs of such technology, that obligation should also be stated clearly in the information about the vendor.

DISPUTE RESOLUTION

Under the proposal, only the physician would have appeal rights in the case of claims that are denied for medical necessity or other reasons. If the vendor dispenses drugs and cannot obtain Medicare payment because the physician's claims are denied, CMS is proposing that the vendor should have the right to complain to its carrier if the losses with respect to an individual physician exceed an "acceptable threshold." If that occurs, the carrier will counsel the physician to submit clean claims and to pursue administrative appeal rights on denied claims. If problems persist, the carrier could recommend to CMS that the physician be suspended from the CAP, and CMS would decide whether to do so.

CAP vendors would also be required to have procedures to handle complaints about service from physicians and about billing issues from patients.

CMS should clarify physicians' responsibilities in the case of denied claims

ASCO agrees with CMS that, under the statute, only the physician has appeal rights with respect to denied claims. We request that CMS clarify the extent of the physician's responsibility to appeal denied claims. We believe that the physician's duty should be only to seek review by the carrier (or redetermination by the carrier under the new appeals regulations). Further appeals

should be at the discretion of the physician, who should be permitted to weigh the chance of success against the expense and burden of the appeal.

The process for resolution of beneficiary disputes should be made clear to beneficiaries

The proposal indicates that beneficiary billing disputes would be handled by the beneficiary first using the vendor's grievance process and, if the beneficiary is dissatisfied with the result, requesting intervention by the vendor's carrier. The carrier would investigate the facts and then facilitate correction to the claim record and beneficiary file.

This process should be made very clear to beneficiaries. We suggest that CMS develop standard language that vendors would be required to include in every bill to beneficiaries explaining the grievance process and the method for subsequently appealing any issues to the designated carrier. The information should make clear that the beneficiary's physician is not involved in the billing and has no authority to resolve any disputes.

CMS and carrier involvement in unresolved disputes

The proposed rule does not set out a clear mechanism for resolution of disputes related to quality of service or beneficiary billing. The preamble states only that the Medicare carrier will attempt to resolve such disputes if the vendor and the physician or beneficiary cannot. We believe that the process should be more definitive. At a minimum, the carrier should be given a clear mandate to resolve disputes, the process for doing so should be clear and should offer the parties an opportunity to participate in a meaningful way, the carrier should have the legal authority to impose a solution, and there should be oversight of the carrier's actions by CMS.

CONTRACTING PROCESS – QUALITY AND PRODUCT INTEGRITY ASPECTS

The proposed regulations include a number of provisions intended to ensure that the vendors provide drugs that meet quality and product integrity standards.

Vendors should be prohibited from opening drug containers

The statute authorizes CMS to impose product integrity safeguards. An issue that the regulations should deal with expressly is the authority of vendors to open drug containers. ASCO is concerned, for example, that if a vendor believes that a particular patient's order does not require a full container of drug, the vendor, acting as a pharmacy, may open a container and dispense only the portion that the vendor believes is necessary by transferring a portion of the drug to another container for shipment to the ordering physician.

Any compromise of package integrity in this manner would be unacceptable. The regulations should clearly require vendors to ship products to physicians in containers that are unopened and otherwise in the same condition as received from the drugs' manufacturers.

Return of damaged or suspicious drugs

The rules should permit physicians to return to the vendor without penalty any drug that arrives in damaged condition or whose integrity the physician reasonably believes may have been compromised. The vendor should not be permitted to require the physician to seek a remedy from the company that delivered the product.

Vendors should be required to carry substantial liability insurance

The proposed financial standards should include a requirement that vendors carry substantial liability insurance. In the event that vendor errors cause harm to patients, their liability for damages could be substantial, and the metrics in the proposed regulations for financial adequacy to conduct a drug distribution business may not be adequate to ensure their ability to pay damages. Thus, liability insurance in sufficient amount to cover potentially serious adverse events should be required.

Vendors should be required to indemnify physicians for any losses they cause

If actions by the vendors in handling the drugs result in injury to patients, it is possible that claims will be made against the physicians who administered the drugs. The regulations should require vendors to indemnify physicians for any losses, damages, and costs (including attorneys fees) incurred by the physician as a result of the vendor's negligence, errors, or omissions.

CMS should audit compliance with and enforce the standards

The only review and enforcement mechanism in the proposed regulations with respect to the quality and other standards appears to be the vendor's certifications that it is in compliance. We believe that CMS should take a more affirmative role in determining vendor compliance by, for example, inspecting vendor facilities, monitoring complaints, auditing vendor compliance with time schedules in the regulations, and so forth.

BIDDING ENTITY QUALIFICATIONS

The proposal notes that vendors would be considered covered entities under HIPAA, including the HIPAA Privacy Rule. ASCO would like to raise two HIPAA issues.

CMS should clarify whether vendors have the right to sell physician-specific data

The CAP vendors will have detailed patient- and physician-specific data about the drug therapies used. Although HIPAA would require vendors to remove patient identifiers before selling or distributing the data, it would appear that the distribution of data with physician identifiers would not violate HIPAA. ASCO requests that CMS clarify whether vendors are permitted to sell or otherwise transfer physician-specific data, or any other data acquired as a CAP vendor, for purposes other than carrying out the CAP contract. If the vendors do have the right to transfer data to third parties for non-CAP purposes, ASCO recommends that CMS require the vendors to disclose their policies on any non-CAP data transfers that they might make so that physicians may take those policies into account in selecting a vendor or deciding whether to participate in the CAP.

CMS should clarify the extent to which vendors may market to patients

The HIPAA Privacy Rule allows covered entities limited rights to contact patients for marketing purposes. CMS should clarify whether the CAP vendors have the right to communicate information to patients other than information related to coinsurance obligations. For example, in the absence of restrictions under the CAP, HIPAA might permit the vendors to provide patients with general health information and information about drugs other than those prescribed by their physician. CMS should clarify the types of information that vendors may provide to patients without their consent.

CAP BIDDING PROCESS – EVALUATION AND SELECTION

New drugs should be available from the CAP immediately or, alternatively, through the reimbursement process

The proposal indicates that adjustments to the vendors' payment schedule will generally be made only annually. There would be more frequent adjustments in certain cases, including introduction of a new drug, but such adjustments would not be more often than quarterly. This proposal implies that a CAP vendor would not be obligated to furnish newly approved drugs to physicians for a period of some months.

It is essential that all newly approved Medicare-covered drugs be immediately available to Medicare beneficiaries. This availability is especially important in the case of new cancer drugs, which may extend beneficiaries' lives. One approach would be for CMS to coordinate with the Food and Drug Administration to learn about the approval of new drugs covered by Part B and to immediately revise the vendor payment schedule to include new drugs. Alternatively, CMS should clarify in the regulations that physicians who have agreed to obtain their drugs from a

CAP vendor are nevertheless free to buy and seek reimbursement for new drugs until they are available from the vendor.

PHYSICIAN ELECTION PROCESS

Physicians would elect annually whether to participate in the CAP, and CMS is proposing that physicians who elect to participate would be required to remain in the program for at least one calendar year. The election would ordinarily take place in the period October 1 through November 15 of each year, but a CAP participating physician could select a replacement vendor mid-year if the selected vendor leaves the program.

Physicians should have the option to elect reimbursement if the selected CAP vendor leaves the program mid-year

CMS seeks comment on the options that should be available to a physician if the physician's selected CAP vendor leaves the program in the middle of the year. ASCO recommends that the physician have the choice of leaving the CAP program or selecting a different CAP vendor. A physician should not be compelled to select a different CAP vendor, since the vendor originally selected by the physician may have been the only vendor acceptable to that physician.

Physicians should have the option to elect reimbursement or change vendors based on problems with the vendor

The proposal allows vendors to exit the CAP midyear and, under certain circumstances, allows a physician to be expelled from the program. The proposal, however, does not include a parallel provision allowing physicians to change vendors or leave the program midyear if the physician's vendor is unsatisfactory. ASCO recommends that the regulations permit such action if the vendor has a record of unsatisfactory service, unresolved disputes, or similar negative acts. For example, the regulations could permit a physician to apply to CMS for permission to leave the program midyear because of dissatisfaction with the vendor, and CMS would grant the application unless the basis for the request was unreasonable.

BENEFICIARY EDUCATION

CMS is proposing to prepare a fact sheet on the CAP program that would be made available to beneficiaries and to physicians who could provide it to beneficiaries. CMS asks for comment on the burden involved in requiring physicians to furnish it to their patients.

CMS should not require physicians to furnish the fact sheet to patients

ASCO appreciates CMS's efforts to develop patient education materials related to the CAP program. We agree that patients who receive a coinsurance bill for drugs from the CAP vendor may be confused. These issues are best handled, however, on a patient-by-patient basis rather than requiring physicians to distribute a CMS fact sheet to every patient. Physicians have an incentive to clear up any confusion on the part of their patients and will take the steps they believe are necessary, which may vary from patient to patient.

CMS MONITORING OF PROGRAM

Finally, ASCO recommends that CMS establish a process for monitoring the effects of the CAP on patient access to drugs and on physician practices, particularly with respect to extra costs imposed on practices. Such a program would permit CMS to identify potential problems and rectify them.

Thank you for the opportunity to comment on the proposed regulations.

Sincerely,

Dean H. Gesme, Jr., MD
Chair, Clinical Practice Committee

54

ORIGINAL

APR

Medical Imaging Contrast Agent Association

April 22, 2005

By Hand Delivery
Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1325-P
Comments on Competitive Acquisition for Medicare Part B Drugs -- Contrast Drugs

Dear Dr. McClellan:

The Medical Imaging Contrast Agent Association (MICAA) is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rule for competitive acquisition for Medicare Part B Drugs (70 Fed. Reg. 10746, March 4, 2005). MICAA represents manufacturers of a distinct category of drugs – contrast agents. MICAA has worked closely over the years with CMS on Medicare coverage, coding and payment policies for contrast agents and the related diagnostic imaging services. Our comments are summarized as follows:

1. HCPCS codes for contrast agents, especially low osmolar contrast drugs, have been significantly changed, effective April 1, 2005, with additional coding changes scheduled to be implemented on July 1, 2005.

2. Medicare payment and coverage policy for contrast drugs has evolved considerably in the past 12 months and physicians are only now learning the new Medicare reimbursement structures for these drugs.

3. Contrast drugs are used exclusively in diagnostic imaging services, such as computed tomography, magnetic resonance imaging, x-ray, and echocardiography.

4. CMS should not implement competitive acquisition for contrast drugs in January 2006, but if contrast drugs are to be included in competitive acquisition at all, they should only be phased in during later years (2007-2008), when the new codes and policies have established an appropriately stable base for such new pricing.

5. CMS should require CAP vendors to provide all drugs represented by a single HCPCS code because products are not identical and patients' clinical needs vary.

6. CMS should consider excluding contrast drugs from competitive bidding because inclusion of contrast drugs in competitive acquisition is:

   a. Not likely to result in significant savings; or

   b. Likely to have an adverse impact on access to such contrast drugs

A. Background on Contrast Drugs and Changing Codes and Reimbursement Policies

Contrast drugs represent a distinct category of drugs that should be phased in or excluded from competitive acquisition. These drugs are used only in diagnostic imaging tests, such as x-ray, CT, MRI and echocardiography. The HCPCS codes for contrast drugs have changed dramatically in the past several months. For many years, there were only 6 codes, which are now being replaced with 20 codes, which are set forth on Attachment A to these comments. Not only have the HCPCS codes changed, but Medicare coverage policy for low osmolar contrast drugs was changed effective January 1, 2005. These significant changes suggest that reimbursement for contrast is in a period of considerable fluidity and competitive acquisition will not effectively achieve any cost savings.

B. Categories of Drugs to be Included under the CAP

1. Phase-In by Drug Category

CMS' proposed rule appropriately cites the authority granted to CMS in the Medicare Prescription Drug Improvement and Modernization Act of 2003 (the "MMA") to establish categories of competitively biddable drugs and phase in the program with respect to those categories beginning in 2006. Contrast drugs could be represented in several categories, such as LOCM (low osmolar contrast material), HOCM (high osmolar contrast material), MR (magnetic resonance) contrast agents, and echocardiography contrast agents or may better be represented in several categories such as LOCM up to 149 mg of Iodine, LOCM 150-199 mg of Iodine etc. as described by the still evolving HCPCS codes. If these drugs are to be included in competitive acquisition at all, they must first be placed in an appropriate category. We note that the clinical and financial features of these products vary widely depending upon whether they are a LOCM, HOCM, MR, or echo contrast agent. Multiple categories will likely be needed. In order to ensure that any application of competitive bidding is feasible, it will take some time to ascertain the appropriate categories, and which products fit into the categories, especially in light of recently established HCPCS codes. Thus, we strongly urge that if contrast agents are to be included in competitive acquisition, that they only be included in later years, such as 2007 or 2008.

2. Provision of Drugs Within a HCPCS Code

MICAA requests that CMS require CAP vendors to provide every National Drug Code ("NDC") associated with a HCPCS code. MICAA believes that allowing CAP vendors to determine which individual drugs within a HCPCS code to provide may jeopardize patient care

and undermine treatment decisions. In the case of contrast drugs, many different products are currently represented by a single HCPCS code. These products vary significantly and are used for different purposes. In short, they are neither interchangeable nor identical. Accordingly, it would be problematic to exclude the majority of contrast drugs from a competitive acquisition program and allow CAP vendors to make only one NDC available to participating physicians.

C. Bases for Excluding Contrast Drugs

The MMA also authorizes CMS to exclude from competitive acquisition a drug or class of drugs if the application of competitive acquisition to the drug(s) is not likely to result in significant savings or it is likely to have an adverse impact of access to such drugs. MICAA urges CMS to exclude contrast drugs because the recently established ASP pricing for contrast drugs is based on the averaging of a number of different manufacturers pricing into the ASP. This classification of many contrast drugs under one HCPCS code has the effect of lowering the ASP and thus achieving cost savings. The marginal savings from competitive acquisition, relative to the newly determined ASP, will not be significant. Consequently, contrast drugs should be excluded from competitive acquisition.

Further, competitive acquisition might result in pricing that essentially disqualifies certain products in certain areas. This could lead to "spot" shortages or serious delays in drug availability. That in turn will lead to adverse impact on access for Medicare beneficiaries.

D. Conclusions

CMS should consider excluding contrast drugs from competitive acquisition, as contrast drugs will not achieve significant savings, and access could be restricted. However, MICAA requests that if CMS is compelled to include contrast drugs in competitive acquisition that CMS phase-in contrast agents into competitive bidding in 2007 or 2008.

MICAA appreciates this opportunity to submit comments to CMS and would welcome the opportunity to meet with CMS to discuss these issues in greater detail. Please feel free to contact MICAA'S Reimbursement Counsel: Gordon Schatz (202) 414-9259 or Gail Daubert (202) 414-9241.

Sincerely,

Jane Majcher
Jane Majcher

Jay Schafer
Jay Schafer

cc: William Thorwarth, M.D. (American College of Radiology)
Pamela Kassing (ACR)

ATTACHMENT A
Summary of HCPCS Codes for Contrast Agents

Part B HCPCS Codes for Contrast Agents – Up to: March 31, 2005

HCPCS Code	Descriptor
A4643	Supply of additional high does contrast material(s) during magnetic resonance imaging, e.g., gadoteridol injection
A4644	Supply of low osmolar contrast material (100 – 199 mg of iodine)
A4645	Supply of low osmolar contrast material (200 – 299 mg of iodine)
A4646	Supply of low osmolar contrast material (300 – 399 mg of iodine)
A4647	Supply of paramagnetic contrast material (e.g. gadolinium)
A9700	Supply of injectable contrast material for use in echocardiography, per study

Effective April 1, 2005, CMS eliminated these "A" HCPCS codes for purposes of billing Medicare Part B and established the "Q" HCPCS codes listed below.

Q9945	LOW OSMOLAR CONTRAST MATERIAL, UP TO 149 MG/ML IODINE CONCENTRATION, PER ML
Q9946	LOW OSMOLAR CONTRAST MATERIAL, 150 - 199 MG/ML IODINE CONCENTRATION, PER ML
Q9947	LOW OSMOLAR CONTRAST MATERIAL, 200 - 249 MG/ML IODINE CONCENTRATION, PER ML
Q9948	LOW OSMOLAR CONTRAST MATERIAL, 250 - 299 MG/ML IODINE CONCENTRATION, PER ML
Q9949	LOW OSMOLAR CONTRAST MATERIAL, 300 - 349 MG/ML IODINE CONCENTRATION, PER ML
Q9950	LOW OSMOLAR CONTRAST MATERIAL, 350 - 399 MG/ML IODINE CONCENTRATION, PER ML
Q9951	LOW OSMOLAR CONTRAST MATERIAL, 400 OR GREATER MG/ML IODINE CONCENTRATION, PER ML
Q9952	INJECTION, GADOLINIUM-BASED MAGNETIC RESONANCE CONTRAST AGENT, PER ML

Q9953 INJECTION, IRON-BASED MAGNETIC RESONANCE CONTRAST AGENT, PER ML

Q9954 ORAL MAGNETIC RESONANCE CONTRAST AGENT, PER ML

Q9955 INJECTION, PERFLEXANE LIPID MICROSPHERES, PER ML

Q9956 INJECTION, OCTAFLUOROPROPANE MICROSPHERES, PER ML

Q9957 INJECTION, PERFLUTREN LIPID MICROSPHERES, PER ML

Subsequently, CMS recognized that additional HCPCS codes were needed to describe contrast agent drugs and established the additional "Q" codes listed below. Note, these "Q" codes are not effective until July 1, 2005.

Q9958 HIGH OSMOLAR CONTRAST MATERIAL, UP TO 149 MG/ML IODINE CONCENTRATION, PER ML

Q9959 HIGH OSMOLAR CONTRAST MATERIAL, 150-199 MG/ML IODINE CONCENTRATION, PER ML

Q9960 HIGH OSMOLAR CONTRAST MATERIAL, 200-249 MG/ML IODINE CONCENTRATION, PER ML

Q9961 HIGH OSMOLAR CONTRAST MATERIAL, 250-299 MG/ML IODINE CONCENTRATION, PER ML

Q9962 HIGH OSMOLAR CONTRAST MATERIAL, 300-349 MG/ML IODINE CONCENTRATION, PER ML

Q9963 HIGH OSMOLAR CONTRAST MATERIAL, 350-399 MG/ML IODINE CONCENTRATION, PER ML

Q9964 HIGH OSMOLAR CONTRAST MATERIAL, 400 OR GREATER MG/ML IODINE CONCENTRATION, PER ML

1020 First Avenue
PO Box 61501
King of Prussia, PA 19406-0901
Tel: 610-878-4583
www.zlbbehring.com

APR

ZLB Behring

April 22, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

ATTN: CMS-1325-P

Re: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B, Proposed Rule

Dear Dr. McClellan:

ZLB Behring is a leading researcher and manufacturer of life-saving biotherapeutics such as blood clotting factors to treat bleeding disorders, including hemophilia and Von Willebrand disease; intravenous immune globulin (IVIG), for the treatment of immune deficiencies; and alpha$_1$-proteinase inhibitor, used to treat alpha$_1$-antitrypsin deficiency, which is commonly referred to as genetic emphysema. We also expect to launch, subject to regulatory approval, a subcutaneous immune globulin in 2005 for the treatment of primary immune deficiency, including more difficult to treat cases. These therapies are created by pooling and manufacturing donated human blood plasma into lifesaving therapies or by recombinant DNA technology.

Thank you for allowing ZLB Behring the opportunity to comment on the proposed rule regarding implementation of the Competitive Acquisition Program (CAP) for Medicare Part B. Section 1847B of the Social Security Act (the Act), created by the passage of the Medicare Modernization Act (MMA), establishes a CAP for the distribution and reimbursement of Part B covered therapies. ZLB Behring will focus its comments on the section of the proposed rule regarding therapies that should be included or excluded from CAP.

Plasma therapies and their recombinant analogs need to be excluded from CAP to assure patient access to these lifesaving therapies. As patient populations for both bleeding disorders and alpha$_1$-antitrypsin deficiency are very small, with only a segment of those being Medicare eligible, a CAP vendor does not have an incentive, nor is it required, to carry all brands within a class. Further, with such small disease states, it is very unlikely there will be substantial savings under CAP when compared to the Average Sales Price plus 6% model (Section 1847A of the

Act). The Secretary of Health and Human Services should follow the precedent set by Congress within Section 303 (b)(1)(E) of the Act, when it exempted IVIG from the CAP, and exercise his statutory exclusion authority for the remaining plasma-derived therapies and their recombinant analogs.

Our comments will focus on the reasons why blood clotting factor and alpha$_1$-proteinase inhibitor should be excluded from CAP:

1) There are only approximately 1100 people Medicare beneficiaries with hemophilia and 2000 with alpha$_1$-antitrypsin deficiency. CAP savings, if any, will be minimal.

2) Patient access will be significantly affected, as CAP vendors are not required, nor have incentive to carry all NDCs within a HCPCS code for such small populations. The brands are therapeutically different, thus optimal medical treatment requires access to all brands of therapy.

3) The precedent for excluding plasma therapies and their recombinant analogs has been established with the statutory exclusion of IVIG.

4) Congress provided CMS with the statutory authority to exclude therapies from CAP if savings would not be realized or if patient access was affected. CMS is required to consider these criteria.

Categories of Drugs to be Included Under the CAP

Section 1847B (a)(1)(D) of the Act authorizes the Secretary of Health and Human Services to exclude competitively biddable drugs and biologicals from CAP if the application of competitive bidding to such drugs and biologicals is not likely to result in significant savings; or is likely to have an adverse impact on access to such drugs and biologicals. As with IVIG, both of these conditions are met when also considering blood clotting factor, alpha$_1$-proteinase inhibitor and subcutaneous immune globulin.

As such, ZLB Behring is concerned with the statement on page 33 of the proposed rule:

> *"We (CMS) do not propose to rely at this time on the Secretary's authority under section 1847B (a)(1)(D) of the Act to exclude competitively biddable drugs and biologicals from the CAP on the grounds that including those drugs and biologicals would not result in significant savings or would have an adverse impact on access to those drugs and biologicals."*

This statement seems to dismiss any adverse impact on access to drugs or biologicals that may result from CAP. The very reason this section was incorporated into the Act by Congress was to prevent negative impacts on access to therapies, specifically therapies to treat small and chronic patient populations. By rejecting the use of this authority in all circumstances, CMS would be threatening access to and quality of care for certain populations. CMS has the obligation to consider requests for exclusion from the CAP under the criteria of Section 1847B (a)(1)(D) of the Act instead of issuing a blanket rejection of exclusion.

Blood Clotting Factors

Blood clotting factors are used to treat bleeding disorders such as hemophilia and Von Willebrand disease in which an individual is missing a protein essential for the blood to clot. Clotting factor replaces this vital protein and acts to discontinue or prevent bleeding episodes that can be disabling or life threatening.

As with IVIG, there are multiple brands of blood clotting factor within a single hospital common procedure code (HCPC). This is unique among most drug and biological HCPC codes but is common for HCPC codes regarding plasma-derived therapies and their recombinant analogs. A primary reason IVIG was exempted from CAP was that multiple brands within the single HCPC code (J 1563) have differing treatment characteristics. This is also common for blood clotting factors as individual patients may respond differently to each of the brands within the HCPC code. Therefore, physicians and patients require access to the range of therapies in order to assure appropriate treatment.

CAP would not guarantee access to each brand of therapy within a HCPC code, thus patient care could suffer. Specifically, page 32 of the proposed rule states:

> *"As discussed in (regulation) proposed §414.908(d), we are proposing that vendors will not be required to provide every National Drug Code associated with a HCPC code"*

With this provision CMS is projecting that brands of blood clotting factor are interchangeable when in fact they are not. As an example, recombinant factor VIII (J 7192) has five brands used in the treatment of hemophilia A. However, the brands are not all of the same composition and individuals react differently to the specific brands. One brand may have a greater possibility than another for the development of an inhibitor, in which the infused protein is viewed as a foreign entity and attacked by the individual's immune system. A patient can develop an allergic reaction to one particular brand and not another due to the varying formulations. Prophylaxis treatment protocols for brands differ and, in some instances, an individual with hemophilia may not achieve

hemostasis as quickly, or at all, by using a particular brand of recombinant factor VIII. Similar issues also apply for other classes of blood clotting factors including, but not limited to anti-hemophilic factor VIII (J 7190); anti-hemophilic factor IX, purified (J 7193); anti-hemophilic factor IX, complex (J 7194); and Von Willebrand Factor Complex (Q 2022).

The Government Accountability Office, when determining an appropriate add-on payment for blood clotting factor under section 1847A of the Act, determined that only 1100 people with hemophilia (out of 17000 in the US) have Medicare as their primary insurer. As the CAP reimbursement rate will be the average of all accepted bids, and the regional CAP vendors will not obtain volume discounts in purchasing as they might with oncology and urology therapies, it is not likely that reimbursement under CAP will be significantly lower than ASP plus 6%. As we are speaking of only 1100 people, the savings, if any, would be small.

The proposed rule and the MMA contain conflicting statements regarding therapies such as blood clotting factors that need clarification. There are those who interpret the statutory definition of "competitively biddable drugs" to exclude blood clotting factor because in most cases it is not administered incident to a physician's service, it is not administered through a DME, and it is usually not dispensed by a regular pharmacy. Additionally, page 22 of the proposed rule regarding therapies not included within CAP states:

> *"Medicare Part B covered vaccines, drugs infused through a covered item of DME, and blood and blood products (not including clotting factor and intravenous immune globulin (IVIG)) are not included in the CAP because they are expressly excluded from section 1842 (o)(1)(c) of the Act."*

Section 303 (b)(1)(F) of the MMA states:

> *"In the case of blood and blood products (other than blood clotting factors), the amount of payment shall be determined in the same manner as such amount of payment was determined on October 1, 2003."*

This section indicates that blood and blood products other than blood clotting factor are exempt from CAP. Yet the above citation from page 22 of the proposed rule links blood clotting factor and IVIG. As IVIG is excluded, is CMS stating that blood clotting factors are also excluded from CAP? Clarification regarding the status of blood clotting factors under CAP is requested so that this important topic can be completely understood.

Alpha$_1$-Proteinase Inhibitor

Weekly infusions of alpha$_1$-proteinase inhibitor help maintain a protective level of alpha$_1$ protein in the blood stream. Without adequate therapy, patients suffer from repeated infections resulting in reduced lung function, hospitalization and reduced quality of life. Others develop relentless, progressive pulmonary emphysema, often leading to premature death. Access to this life-saving therapy is critical in maintaining lung function, thus life itself.

As with blood clotting factors and IVIG, there are multiple products within the HCPC code for alpha$_1$-proteinase inhibitor (J 0256). At present, there are three brands of therapy that are included within J 0256, two of which have recently been introduced to the market and one that has been available for approximately 15 years. ZLB Behring is concerned that a regional vendor would only supply the single, older therapy and neither of the two newer therapies that represent different treatment options for alpha$_1$-antitrypsin deficiency.

According to the Alpha-1 Foundation, approximately 5000 individuals in the United States have been diagnosed with alpha$_1$-antitrypsin deficiency, of which approximately 40% are Medicare beneficiaries. With such a limited number of beneficiaries, CAP would not result in substantial savings compared to ASP plus 6%. Further, the CAP vendor may not have the financial ability and desire to provide access to all brands for such a small population. The Secretary of HHS should use his exclusion authority to exempt alpha$_1$-proteinase inhibitor from CAP for both the lack of savings and the negative impact on access that would occur.

Subcutaneous Immune Globulin

As previously indicated, ZLB Behring plans to introduce a subcutaneous immune globulin to the United States market in the latter half of 2005. We believe this therapy will be an innovative step in the advancement of immune globulin for treating individuals with primary immune deficiency, including treatment of patients who have difficulty tolerating intravenous traditional methods of administering immune globulin. ZLB Behring seeks confirmation that the CAP exclusion for IVIG would also apply to this version of immune globulin that will be used to treat many from the same primary immune deficient population. ZLB Behring believes that in excluding IVIG from CAP, Congress intended to ensure access to immune globulin therapy for conditions like primary immune deficiency and not solely the intravenous delivery method currently utilized. To exempt IVIG but not the subcutaneous therapy would disadvantage access to a new approach in treatment that could benefit segments of the immune deficient population. Therefore we request that CMS explicitly exempt subcutaneous immune globulin from CAP implementation.

Conclusion

Congress saw the need to exempt IVIG from CAP, given the need for patients and physicians to have available the multiple brands of therapy contained within an individual HCPC code and the belief that contracted vendors would not be able to assure access given the small patient population. The same rationale holds true for blood clotting factors and alpha$_1$-proteinase inhibitor. Both types of therapy have multiple brands within a HCPC code, both are derived from human blood plasma or a recombinant analog, and both therapies have multiple brands within a HCPC code that are not interchangeable. In fact, it is our understanding that members of Congress have expressed to CMS their concerns and desire to have these therapies exempted from the CAP through the use of the Secretary's exclusion authority. Unlike therapies with wider utilization such as oncology and urology, each plasma or recombinant analog therapy is utilized in such a small scope that savings under CAP cannot be assumed when compared to ASP plus 6%. And, no single vendor is likely to stock all brands of therapies, even if they so desired, for these rare conditions given the very small populations in each likely competitive bidding geographic area. The probable scenario would be a bidder limiting access to much less than the full range available within a HCPCS code. A number of treatment providers still would rely on that system rather than seek to administer the products under the ASP alternative. Alternative providers stocking more brands also would be less available once a bid is awarded to vendors given the small populations.

ZLB Behring requests that blood clotting factors, alpha$_1$-proteinase inhibitor and subcutaneous immune globulin be treated in a similar manner as IVIG and exempted from CAP. It is our hope that the Secretary of HHS will use his exclusion authority, thus ensuring that patients with these rare conditions will continue to have access to all life-saving brands of plasma and recombinant analog therapies.

As you likely are aware, the Immune Deficiency Foundation reports that changes in reimbursement enacted in part B for IVIG under the MMA have resulted in some physicians no longer administering IVIG, or the desired brand. Individuals at CMS now are trying to explore ways to restore access. Access to clotting factor experienced strong challenges under part B after reimbursement transitioned to ASP plus, and CMS agreed to increase the add-on payments after considerable patient anxiety and problems with access. There has been substantial industry consolidation given the challenges in producing these complex biotherapies for small populations and long-term access to brands has to be considered. These instances, and others in history, demonstrate that delivery of therapy to these small populations really is a delicate balance that does not lend itself to approaches possibly suitable for broadly distributed products. The best way to avoid having to make a fix after CAP is implemented is to learn

from these lessons and the reality of these markets, and exempt the abovementioned plasma therapeutics from CAP when the final rule is issued.

We would be very happy to meet in person or by teleconference to discuss in more detail. Should there be any questions or if we may be of assistance, please feel free to contact me or Patrick Collins (610-878-4311). Your consideration of our comments is greatly appreciated.

Sincerely,

Dennis Jackman
Senior Vice President, Public Affairs

APR 26 2005

ORIGINAL

April 25, 2005

VIA HAND DELIVERY

The Honorable Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: File Code CMS-1325-P

Dear Administrator McClellan:

On behalf of Alcon, Inc. I wish to thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") Notice of Proposed Rulemaking (the "Proposed Rule") regarding the Medicare Competitive Acquisition of Outpatient Drugs and Biologicals under the Part B program (hereinafter referred to as "CAP").[1] Alcon, Inc. is the world's largest developer, manufacturer and marketer of ophthalmic pharmaceuticals, ophthalmic surgical equipment and devices, contact lens care products, and other consumer eye care products that treat diseases and conditions of the eye. Our products are used to treat a variety of eye diseases and conditions including cataract, retinal disease, glaucoma, and refractive error. This broad range of products represents the strongest portfolio in the ophthalmic industry.

Increasing the ability of physicians to focus on patient care rather than administrative requirements of drug acquisition is a common-sense concept that should be implemented as quickly and broadly as possible. Alcon has every confidence that CMS will design a system capable of effectively implementing the CAP. Nevertheless, as a manufacturer of pharmaceuticals that may be part of CAP, Alcon believes that in order for the program to be successful CMS must ensure that: Medicare beneficiaries have access to all clinically appropriate pharmacologic therapies, the program is open to physicians of all specialties, CAP vendors are not involved in medical necessity determinations, and reimbursement for physicians' professional services are adequate to cover the cost of drug administration and participation in the CAP program. To this end, we offer the following general comments.

I. Implement Broad Access to CAP

The success of CAP will depend largely on the number of physicians, vendors and manufacturers that participate in the program. Therefore, CMS should not restrict the categories of drugs which may be purchased under CAP to those prescribed only by certain medical specialties. CAP likely will be a welcome option for many physicians who find the costs of acquiring and billing

[1] 70 Fed. Reg. 10746 (March 4, 2005).

for drugs and biologicals and the related coinsurance to be overly burdensome. Our experience suggests that certain smaller group practices and solo practitioners find drug acquisition particularly burdensome, and as a result it can negatively affect a physician's decision whether to offer a treatment. The CAP program offers the first real relief to physicians. For that reason, all physicians who administer drugs in their office should have an equal opportunity to realize the intended benefits of CAP.

While we commend CMS for considering whether a phase-in would result in a smoother transition to the CAP, we are concerned that a phased in implementation approach could negatively affect the long-term success of the program. A gradual phase-in not only singles out certain physicians and therapies for special treatment, it also will hinder CMS' ability to gain a complete and accurate assessment of the operational issues that must be addressed to support broad adoption of the program in a timely manner as envisioned by Congress. For example, if the program is open only to a single specialty CMS will not gain any experience with how vendors deal with the inherent differences in the types of drugs provided through the Part B program. In addition, a restricted set of drugs will limit the participation of manufacturers in the program and could decrease the number of vendors willing to participate in the CAP. In order for vendors to participate in the CAP, the program must be structured to provide financial benefits to vendors. If CMS limits the scope of services a vendor may offer to physicians this necessarily limits the vendors flexibility in developing a mix of products that ensure the vendor can offset losses resulting from the sale of certain drugs against gains derived from others. CMS must promote vendor participation, not artificially restrict it.

II. Ensure Beneficiary Access to Clinically Appropriate Therapies

CAP should not interfere with patient access to critical therapies. The CAP program was created to help eliminate legitimate concerns that patient access to important pharmacologic and biologic therapies were being adversely affected due to the financial risk and administrative burdens experienced by physicians in acquiring certain products. CMS must not frustrate the goal of the CAP by structuring the program in such a way that it interferes with clinical decision-making or restricts physicians' therapeutic choices.

A. Range of products

CAP vendors must be expected to provide physicians with a sufficiently broad range of drugs and biologicals to meet Medicare beneficiaries' unique needs, including access to new drugs and biologicals. As noted by CMS, the Social Security Act (SSA) section 1847B(b)(1) requires prospective CAP vendors to bid on "at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area."[2] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) Conference Report made clear that this requirement applies to all drugs and biologicals. The report states that competition be conducted "among entities for the acquisition of at least one

[2] 70 Fed. Reg. at 10751.

competitively biddable drug or biological that is a multiple source or a single source drug or biological within each billing and payment code within each category for each area."[3]

The Final CAP Rule should be clear that every CAP vendor must offer at least one drug or biological within every HCPCS code that falls under a category chosen by CMS for CAP. We are concerned that without such direction, CAP vendors will not offer drugs with a low utilization rate or drugs that become available during the term of the contract.[4] The final rule also should explain that when there is only one product covered by a HCPCS code, as is true with many ophthalmology products, and that therapy falls within a CAP category, each vendor submitting a bid for that category must be required to offer at least one formulation (as represented by a National Drug Code or NDC) of that drug or biologic.

CMS also should determine how newly approved drugs for which a HCPCS has yet to be established will be paid under CAP. As a practical matter, new drugs may not meet the window for applying for a new HCPCS code, or may not otherwise have been assigned a HCPCS code, and, consequently, must be billed under the miscellaneous J Code. Because the J Code serves as a "catch-all" code, the cost and utilization of the drugs under that code vary significantly. The Proposed Rule does not provide any guidance on how these products will be handled under the CAP program. The Final CAP Rule should provide direction related to drugs billed under a miscellaneous code.

Finally, CMS should clarify that the CAP vendor's requirement to provide at least one NDC per drug or biological in a HCPCS code does not impose any forced sale requirements on manufacturers. Although Congress mandated that CAP vendors offer one drug for each HCPCS code in a category, the statute does not grant CMS any authority to intervene in the relationship between CAP vendors and manufacturers or distributors,[5] or to interfere with a manufacturer's exclusive contract with a distributor. CAP vendors can acquire drugs and biologicals as required by the statute while respecting manufacturers' existing distribution agreements by seeking to obtain the drugs or biologicals from the sole distributor.

B. No formularies

Industry reports suggest that potential CAP vendors are urging CMS to grant them the right to construct CAP formularies. Alcon does not believe that the statute permits CMS to promulgate such a regulation. Furthermore, the creation of formularies would conflict with the clear Congressional mandate that CAP vendors offer at least one drug or biological for every HCPCS

---

[3] H. Rep. No. 108-391, at 594 (2003). The legislative history also clarifies that "billing and payment code" means a HCPCS code. H. Rep. No. 108-391, at 594 (2003).

[4] The proposed bidding process does not create an incentive for CAP vendors to provide expensive drugs that have minimal or no utilization based on the 2004 Medicare data. Utilization statistics necessarily will lag behind current physician demand for a newly approved drug as physicians gain knowledge and experience with the drug clinical profile. CMS should clarify how updated utilization statistics will be incorporated in the bidding process.

[5] See 70 Fed. Reg. at 10759 (statute requires vendors to acquire drugs and biological products "from the manufacturer or from a distributor that has acquired the products directly from the manufacturer").

code within a CAP category. Accordingly, the final rule should state affirmatively that vendors do not have the authority to construct formularies and that they must supply "at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area."

III. CAP Should Not Adversely Impact Clinical Decision-Making

A. Physicians, not CAP vendors, should make medical necessity decisions

The Proposed Rule states that physicians and their local carriers will continue to be responsible for determining whether a drug or biologic is being used consistent with any local coverage determinations (LCDs).[6] The Proposed Rule does not address whether the CAP vendors would perform a similar review before shipping a drug or biological. Alcon believes the decision regarding whether a drug or biological is appropriate for a given patient must remain with the physician. We urge CMS to clarify that the CAP vendors will have no authority to withhold, delay or stop a shipment of a drug on the vendor's list that is ordered by a physician. Such an action by a CAP vendor could impede a beneficiary's course of treatment and recovery. Thus, the Final Rule should reiterate the commitment the agency made to the Practicing Physician Advisory Council (PPAC) -- that nothing in the CAP program will in any way modify the existing coverage process, and that vendors must supply drugs, whether or not they are ordered for off-label uses.[7] If the local carrier determines that the drug or biologic is not covered, it can deny coverage and inform the designated carrier to withhold payment from the vendor. In all cases, physicians, not CAP vendors, must decide what therapy the patient will receive.

B. The "furnish as written" option

Alcon commends CMS for including the "furnish as written" option as part of the CAP proposal. This option recognizes that there could be instances where physicians may not be able to obtain from a CAP vendor the specific formulation of a drug or biologic that a patient needs. In these cases, CMS proposes to allow physicians to purchase the drugs from another source and to bill Medicare using the ASP methodology.[8] Alcon supports this proposal, recommends it be finalized and urges CMS to allow physicians to exercise this option with as minimal an administrative burden as possible.

C. Physicians should be permitted to choose the categories of drugs they will obtain through the CAP

CMS requests comment on "whether physicians must obtain all categories of drugs that a particular CAP vendor provides from the vendor, or whether the physician should be able to

---

[6] Id.
[7] "Competitive Acquisition Vendors Should Pay Drug Returns – CMS Doctor Panel," The Pink Sheet, Mar. 14, 2005, at 25.
[8] 70 Fed. Reg. at 10755.

choose the categories he or she wishes to obtain from the vendor."[9] Section 1847B(a)(1)(A)(iii) of the SSA states that physicians are allowed to chose the "contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician." Thus, the statute itself seems to require that physicians be given the option to select a different vendor for each CAP category, rather than be limited to one vendor. The Final Rule should clarify that physicians may obtain drugs and biologicals from multiple vendors. The Final Rule also should reiterate that physicians continue to have the option to purchase drugs for their office and be reimbursed at ASP+6%.

IV. Minimize the Clerical and Administrative Burdens on Physicians

While physicians are encouraged by the prospect of the CAP, there also is concern about the potential administrative burdens of participating in the program. In the Proposed Rule, CMS states that it does not believe the clerical and inventory resources associated with participating in the CAP exceed the costs of purchasing and billing for drugs under the ASP system.[10] We urge CMS to review its proposed requirements and consider input from physicians to ensure that the process is as streamlined as possible. For example, CMS anticipates that carriers will perform post-payment review when physicians use the resupply or "furnish as written" options.[11] Although we understand CMS' desire to monitor compliance with the CAP rules, frequent audits would increase the burdens associated with participating in the CAP. Physicians' administrative burdens also may be greater under the CAP than under ASP-based reimbursement because of requirements to maintain a separate electronic or paper inventory for each CAP drug obtained and to file the Medicare claim within 14 days of the date of drug administration.[12] CMS also proposes to require physicians to provide a patient's height and weight on the order,[13] yet this information is unnecessary because the physician not the vendor is responsible for determining proper dosing. To the extent possible, CMS should attempt to further streamline the administrative burdens imposed on physicians participating in CAP. The agency also should consider making payments to physicians that elect CAP to compensate them for the increased costs of participation in the program.

V. Conclusion

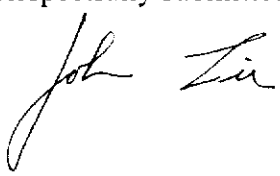
Congress intended the CAP to provide physicians with an alternative method of acquiring drugs and biologicals for their patients. It will succeed only if it offers physicians less administrative and financial inconvenience while also ensuring continued patient access to essential therapies. Alcon strongly supports the implementation of the CAP and applauds CMS' efforts to ensure the effectiveness of the program. The potential benefits of the CAP program are clear: better patient care and increased administrative efficiency. Because the benefits of the CAP are significant, Alcon encourages CMS to fully implement the program on January 1, 2006 without arbitrary

---

[9] Id. at 10755.
[10] 70 Fed. Reg. at 10755.
[11] Id. at 10756.
[12] Proposed 42 C.F.R. §414.908(a)(3).
[13] Id.

limits on the types of drugs covered and the types of physicians who may participate. Furthermore, CMS must take the necessary steps to ensure vendors receive financial benefits from participation in the CAP, otherwise a lack of vendor participation may result and the benefits of the CAP will be limited.

Respectfully submitted,



John C. Liu
Director of Reimbursement
Global Marketing, Retinal Pharmaceuticals

57

ACP

AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

APR 26 2005

April 25, 2005

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 303-D
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on the Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals under Part B Proposed Rule (CMS-1325-P).

Dear Dr. McClellan:

The American College of Physicians (ACP), representing over 116,000 doctors of internal medicine and medical students, is pleased to submit comments on proposed rule CMS-1325-P --- "Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals under Part B Proposed Rule." ACP appreciates the efforts of the Centers for Medicare and Medicaid Services (CMS) in proposing an alternative to the current practice of physicians buying and billing for drugs under the current average sales price (ASP) system.

The College is limiting its comments to some general, basic concerns regarding the proposed Competitive Acquisition Program (CAP) since most of our members purchase a low volume of drugs. We are requesting your attention to the following issues to help ensure effective implementation of the CAP for outpatient drugs and biologicals:

1. The requirement for physicians to bill claims within 14 calendar days of the date a drug acquired through the CAP was administered.

   The 14 day requirement for submitting drug administration claims is a radical change from the current 1 year window and will impose an excessive burden in many practice settings. In light of the need for claim submission for vendors to receive payment, the College proposes 30 business days to bill claims as a reasonable compromise. In addition, any penalty for late submission should be preceded by a warning protocol implemented by the local carrier.

2. The decision not to make a separate payment to physicians for the clerical and inventory resources associated with participation in the CAP program.

   The proposed rule states that CMS does not believe that the clerical and inventory resources associated with participation in the CAP exceed the corresponding

resources associated with the ASP program. Since these resources are already bundled into the physician drug administration payment, CMS is not proposing any separate or additional payment to cover the clerical and inventory resources associated with participation in the CAP. The ACP disagrees with the underlying assumption of equivalent resource expenditures between the CAP and ASP programs. More specifically, we believe the CAP program will entail the use of more clerical and inventory resources than under the ASP system from such activities as needing to include additional information on the prescription form, having to repeatedly acquire drugs linked to each patient as opposed to more bulk purchasing, having to return drugs that are not administered, and having to appeal a larger number of denials solely to ensure that the vendor receives payment. Preferably, a tight, well designed study can be conducted by CMS prior to implementing the final rule to assess the actual resource costs under the CAP program and this payment issue can be resolved based on the obtained data. At a minimum, we would expect that this data be collected following implementation of the program and payment modifications be made as necessary.

3. The requirement that a physician must acquire <u>all drugs listed in a category</u> from a chosen vendor to participate in the CAP.

   The ACP recommends that the requirement that a physician must acquire all drugs listed in a category from a chosen vendor to participate in the CAP be removed. This requirement will serve as a barrier for many of our members to participate in the program. The primary benefit of the CAP for many physicians would be the ability to acquire those specific drugs that are not easily available and/or are only available at a prohibitive price. This current restrictive requirement substantially reduces physicians' ability to choose which drugs to acquire through CAP, and thus, reduces the overall value of the program.

4. The availability of adequate patient protections related to vendors' collection of applicable co-payments and deductibles.

   The College is concerned that the issue of adequate patient protections surrounding vendors' collection of applicable co-payments and deductibles was not adequately addressed in the proposed rule. The proposed rule does outline a grievance process for the beneficiary to follow if they have a problem with the vendor's billing. It doesn't address the availability of patient protections ensuring that medications are not inappropriately discontinued for a patient due to the vendor encountering difficulty in collecting applicable copayments and deductibles. Furthermore, it doesn't address the availability of patient protections ensuring that abusive collection tactics are not employed by the vendor. We request that you directly address these issues in the final rule.

5. The release of an interim final rule for the CAP rather than a final rule.

   Physicians, vendors and the Agency are embarking on an entirely new endeavor with the implementation of the competitive acquisition program for Part B drugs. Many program decisions will be made without any pilot testing or direct previous experience to ensure their effectiveness. Thus, it is highly likely that the program will require modifications following implementation. The ACP recommends that the CAP initially be implemented under an interim final rule that will provide an extended opportunity for public comment and facilitate the approval of required program modifications.

We are aware that a number of the medical specialty groups are very interested in the CAP, and plan to send comment letters addressing additional concerns in the areas of program scope, administration, financial and legal liability, and patient protection. The ACP encourages you to adequately address these additional concerns in the final rule.

The ACP appreciates this opportunity to comment on the proposed CAP standards. Please do not hesitate to contact Neil Kirschner on the ACP staff at 202 261-4535 and nkirschner@acponline.org if you have any questions regarding the submitted comments.

Sincerely,

Joseph W. Stubbs MD

Joseph W. Stubbs, MD, FACP

58

APR 26 2005

The Hemophilia Coalition
1401 H Street, N.W., Suite 560, Washington, D.C. 20004
T: (202) 898-6360 F: (202) 898-6366

Embargoed until 4/26/05 at 5:00 P.M.

April 26, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals under Part B; Proposed Rule. File Code CMS-1325-P (70 Fed. Reg. 10745, March 4, 2005)

Dear Dr. McClellan,

The Hemophilia Coalition appreciates this opportunity to provide its formal comment on the Notice of Proposed Rulemaking (NPRM) for the Competitive Acquisition of Outpatient Drugs and Biologicals under Part B of the Medicare program, implementing Section 1847B of the Social Security Act (the Act) as enacted in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The Coalition's comments are specifically related to the section of the Proposed Rule which discusses the categories of drugs to be included under the Competitive Acquisition Program (CAP).

The Hemophilia Coalition is comprised of three national, full-service hemophilia homecare providers who provide blood clotting factor and clinically appropriate related items and services to both Medicare and non-Medicare patients. Our members currently provide full-service hemophilia homecare in all 50 states and provide hemophilia care to greater than 42 percent of all Medicare hemophilia patients. Full-service hemophilia homecare providers offer patients a wide range of vital services integral to ensuring that hemophilia patients are managed in a manner to optimize clinical outcomes and reduce hospitalizations and emergency room visits. Our coalition members are the three largest national full-service hemophilia homecare providers—Caremark, Inc., Curative Health Services, Inc., and Hemophilia Health Services Inc.

Caremark Rx, Inc. is a leading pharmaceutical services company, providing through its affiliates comprehensive drug benefit services to over 2,000 health plan sponsors and their plan participants throughout the U.S. Caremark's clients include corporate health

plans, managed care organizations, insurance companies, unions, government agencies and other funded benefit plans. The company operates a national retail pharmacy network with over 57,000 participating pharmacies, seven mail service pharmacies, the industry's only FDA-regulated repackaging plant and 21 specialty pharmacies for delivery of advanced medications to individuals with chronic or genetic diseases and disorders. Caremark has been one of the largest national specialty pharmacy providers of products and clinically appropriate services to the hemophilia community for more than 26 years. Caremark provides client centered comprehensive care led by single point of contact clinical teams. Specialized data collection ensures therapeutic compliance and appropriateness of home clotting factor treatment.

Curative Health Services, Inc. became a full-service hemophilia homecare provider in 2001. Curative has tapped its proven success strategies to provide what the hemophilia community demanded - reliable, cost efficient and high quality products and services. Curative's Specialty Infusion business, through its national footprint of over 40 local pharmacy branches, provides products and related clinically appropriate services to individuals with chronic or severe conditions such as hemophilia and other bleeding disorders. Curative's hemophilia homecare approach focuses on providing highly personalized services including education for patients, families and providers, community outreach programs and self-infusion training. Currently the third-largest hemophilia homecare provider, Curative is deeply committed to creating a better world for the bleeding disorders community, and empowering them to live full, healthy and productive lives.

Founded in 1990 by a family living with hemophilia, Hemophilia Health Services, Inc. has grown quickly to become the largest healthcare company in the United States focusing exclusively on hemophilia. In addition to providing factor products, HHS also supplies clinically appropriate patient services for people with hemophilia and related bleeding disorders. Hemophilia Health Services' FactorCare program includes clinical case management and managed care networking, patient and provider education, community advocacy, outcomes tracking, psychosocial support, and home infusion training. HHS reports patient compliance and factor usage in addition to tracking self-reported data by our clients.

Overview of Coalition Comments

The Hemophilia coalition believes that blood clotting factor should be excluded from the CAP program for the following three reasons: there are clear statutory and administrative limitations which prevent CMS from including drugs and biologicals outside the physician office setting in CAP; it is unnecessary to include blood clotting factor in CAP because it is primarily infused outside the clinical environment and inclusion of blood clotting factor in CAP for the physician office setting would not result in significant cost savings for the Medicare program.

CMS Has Clear Statutory And Administrative Limitations Which Prevent Inclusion of Drugs and Biologicals Administered Outside the Physician Office Setting CAP

Section 1847B(a)(2)(A) of the Act defines "competitively biddable drugs and biologicals" as "a drug or biological described in Section 1842(o)(1)(C) and furnished on or after January 1, 2006." While blood clotting factor therapies fit within this broad potential universe of products, the Hemophilia Coalition believes that the rest of the provisions directing implementation of the CAP in Section 1847B of the Act are clear that the CAP can only apply to drugs and biologicals administered incident to a physician's services, and therefore cannot apply to blood clotting factors furnished and administered to hemophilia patients in the home. For example, as CMS points out in the Proposed Rule, provisions in Section 1847B make it clear that "the election to participate in this program rests with physicians,"[1] and that payment for drugs and biologicals in CAP is conditioned on administration of those drugs.[2] Hemophilia Coalition members provide blood clotting factor and clinically necessary related items and services to hemophilia patients for administration in the home. Our member companies then bill and are reimbursed by Medicare directly under Part B of the program. Hemophilia homecare providers are not physicians, and under the mechanisms set forth in Section 1847B of the Act, our Coalition members would not be able to make the election to participate in CAP. The statute also conditions payment for competitively biddable drugs and biologicals on administration, and in the Proposed Rule, CMS proposes that payment cannot be made for a drug or biological until the physician has submitted a claim for administration services with a prescription number that matches the vendor's claim for the drug.[3] Because blood clotting factor provided by Hemophilia Coalition members is not administered in a physician's office, there would be no claim for administration services submitted to the Medicare local carrier.

It is Unecessary and Inappropriate to Include Blood Clotting Factor In CAP Because It Is Primarily Infused Outside the Clinical Environment

Through the scientific development of blood clotting factor and the emergence of hemophilia homecare providers and their related services, hemophilia patients have been empowered to infuse blood clotting factor primarily outside the clinical environment. This evolution over the past forty years has in fact changed the standard of care in the treatment of hemophilia. Patients are now able to treat their disease when and where a bleed occurs, which has been proven by medical literature and data to be the most critical time period for patients to infuse. The ability of hemophilia patients to infuse blood clotting factor outside the clinical environment has improved their health outcomes and reduced costs in the health care system by reducing the need for physician, hospital and emergency room visits.

[1] Proposed Rule, p. 23.
[2] Section 1847B(a)(3)(A)(iii)(II) of the Social Security Act (the Act).
[3] Proposed Rule, p. 51.

Inclusion of Blood Clotting Factor in CAP for the Physician Office Setting Would not Result in Significant Cost Savings for the Program

The Coalition urges CMS to use its exclusionary authority in Section 1847B(a)(1)(D) of the Act to exclude blood clotting factor from the CAP because we do not believe that inclusion of blood clotting factor will result in significant savings for the program. As we stated above, the standard of care for hemophilia treatment today is for patients to infuse primarily outside the physician office setting. Because the vast majority of blood clotting factor infusions are not administered in a physician's office, and because the Medicare hemophilia patient population is so small, including blood clotting factor in the CAP when used in a physician's office is not likely to result in significant savings to the Medicare program.

Should CMS exclude blood clotting factor from the CAP as the Hemophilia Coalition recommends, physicians would still have a mechanism by which to acquire and administer these therapies to Medicare hemophilia patients. In the rare instances when it is necessary for a physician to administer blood clotting factor to a patient, he or she would retain the ability to purchase the product, bill Medicare directly and be reimbursed at 106 percent of the Average Sales Price (ASP).

Background on the Treatment of Hemophilia

Hemophilia is a rare genetic bleeding disorder caused by a deficiency or lack of blood clotting factor. Clotting factor is needed to stop bleeding after a cut or injury and to prevent spontaneous bleeding. If left untreated, hemophilia patients can experience severe internal bleeding that can lead to disability or death. There are two major types of hemophilia—Hemophilia A and Hemophilia B. Hemophilia A is caused by a deficiency of active clotting factor VIII, whereas Hemophilia B results from a lack of active clotting factor IX. Approximately 15,000 to 20,000 individuals in the United States suffer from hemophilia, 1,100 of which are Medicare beneficiaries.

Until 1965, the only available treatment for hemophilia, other than using rest and ice, was whole blood or fresh-frozen plasma transfusions that could only be given in hospitals. These transfusions were only partly effective because the body cannot hold the large amounts of fluid needed to provide enough clotting factor to control bleeding fully. In 1965, a medical breakthrough ended the need for high-volume whole plasma transfusions for persons with hemophilia A. Dr. Judith Graham Pool discovered cryoprecipitate, the factor-rich component of blood. Cryoprecipitate allowed for easier, more effective, and more efficient treatment because less fluid had to be transfused into the patient. By the early 1970s, clotting factors VIII and IX became widely available in a new concentrated, freeze-dried form. This made it possible for people to receive treatment on an outpatient basis or through full-service hemophilia homecare companies.

Today, hemophilia is primarily treated by replacing a patient's missing blood clotting factors. The clotting factors are collected from human donors or produced in a lab using recombinant DNA technology, and administered to the patient. Patients typically receive

clotting factor for home use from full-service hemophilia homecare providers or from certain Hemophilia Treatment Centers (HTCs). Approximately 67 of the nation's 148 HTCs currently provide clotting factor for use in the home.

On average, an individual with severe hemophilia uses 78,000 units of clotting factor per year. The Medicare hemophilia patients served by members of the Hemophilia Coalition use, on average, on average, 150,000 units per year. Medicare beneficiaries use more factor than the general population because they are predominantly adults and hemophilia treatment is based on weight. The average cost of hemophilia treatment is a $100,000 per year. However, these costs can vary widely across the patient population, depending on the severity of their illness or injuries.

Background on the Medicare Hemophilia Patient Population

According to the GAO report, 6 percent of the hemophilia population, or about 1,100 individuals, are Medicare beneficiaries. The average age of a Medicare beneficiary with hemophilia is 53, nearly three decades older than the average age of the total hemophilia population, which is 24. In addition, the GAO report states that Medicare beneficiaries with hemophilia show higher rates of chronic joint disease and two viral infections, hepatitis C and human immunodeficiency virus (HIV), than the general hemophilia population.[4]

From approximately 1978 until approximately 1985, many of the blood clotting factor products that came from human plasma donors were contaminated with HIV, the virus that causes AIDS, and the Hepatitis C virus. Because many Medicare beneficiaries began using clotting factor products before the blood supply was tested for hepatitis C and HIV and before recombinant products were available, the GAO estimates that beneficiaries have high rates of infection with those viruses: 60 percent have the hepatitis C virus and 45 percent have HIV. These patients experience higher rates of co-morbidities and require extensive clinically appropriate services. For the total hemophilia population, the rates of hepatitis C and HIV infection are 39 and 24 percent, respectively.[5] The Centers for Disease Control and Prevention's Universal Data Collection Program found that 30 percent of adults with hemophilia (ages 21-60) are infected with HIV.[6] Thus, co-infected patients need additional education and medication monitoring to support drug to drug compatibility. Full-service hemophilia homecare providers must also be proactive in their efforts to ensure that Medicare beneficiaries comply with the treatment protocols established by their physician. In addition, these patients often work with several physicians requiring more resources than unaffected hemophilia patients.

---

[4] U.S. Government Accountability Office, *Payment for Blood Clotting Factor Exceeds Providers' Acquisition Costs*, GAO-03-184 (Washington, D.C.: GAO 2003). Hereafter referred to as GAO Report.

[5] GAO Report, p. 7.

[6] U.S. Centers for Disease Control and Prevention, *Report on the Universal Data Collection Program*, Volume 6, Number 1, March 2004 (Washington, D.C.: CDC, 2004).

Background on Full Service Hemophilia Homecare

By the mid to late 1970's, home infusion of clotting factor emerged as a viable treatment modality for hemophilia. HTCs provided extensive training and education to persons with hemophilia to allow them to perform home infusion of blood clotting factor. Prior to the advent of home infusion, individuals with hemophilia would have to travel to their local HTC (often located a great distance from the beneficiary) or local emergency room (ER) once an active bleed had occurred.

The provision of blood clotting factor and clinically appropriate items and services in the home represented a major advance in hemophilia care. Home care transformed hemophilia treatment from a reactive response to an acute bleed, to a proactive measure that minimizes the lifelong debilitating nature of the disease and the progressive crippling orthopedic effects of hemophilia. Benefits of hemophilia home treatment also include:

- Quicker treatment and fewer complications of bleeding which lead to other co-morbidities and higher cost
- Reduced pain
- Self infusion avoids costly emergency room visits
- Prompt infusion of blood clotting factor reduces joint destruction and costly replacement surgeries
- Effective early treatment lessens need for inpatient hospital stays

Full-service hemophilia homecare companies currently provide a broad range of critical patient-focused, clinically appropriate items and services that are not generally provided in HTCs. In addition to providing blood clotting factor, members of the Hemophilia Coalition provide the following clinically appropriate items and services to their hemophilia homecare patients:

- Home or office delivery of blood clotting factor and supplies
- Educational materials and programs
- Medically necessary ancillary supplies
- Emergency telephone support 24 hours a day, seven days a week by nurses and pharmacists trained in hemophilia
- Emergency delivery of blood clotting factor
- Pharmacist, nurse, and/or a case representative assigned to each patient
- Compliance programs
- Notification of product recalls or withdrawals
- Visiting nurse services
- Waste disposal services
- Assay to prescription management
- Factor utilization reports

The clinically appropriate items and services the Coalition's members provide lead to fewer emergency room visits and hospitalizations, less frequent bleeds, less units infused, and an improved quality of life for the patient.

Full-Service Hemophilia Homecare Providers—Improving Patient Outcomes

A report prepared by the Centers for Disease Control and the state health departments of Colorado, Georgia, Louisiana, Massachusetts, New York, and Oklahoma found that hemophilia patients receiving hemophilia homecare were 20 percent less likely to experience a hospitalization due to a bleeding complication. The study included 2,650 hemophilia patients (approximately 20 percent of the hemophilia patients in the United States) and tracked those patients for four years. The report concluded that "the introduction of HTCs and home therapy has proven to be effective in reducing the risk of hospitalization due to bleeding complications."[7]

Full-service hemophilia homecare providers and clinically appropriate items and services have also been embraced by many health plans. For example, Blue Cross Blue Shield of Minnesota implemented a hemophilia homecare and patient education program which lead to a 67 percent reduction in emergency room visits for hemophilia patients and an 80 percent decrease in the average number of hospitalizations for hemophilia patients. Each time that a full-service hemophilia homecare provider prevents a patient hospitalization, payors save an average of $4,000 per episode. Full-service homecare providers also monitor patient compliance with a physician's recommended dosing instructions to ensure that the patient does not infuse more factor units than prescribed, potentially saving thousands of dollars per year.[8]

Current Medicare Reimbursement for Hemophilia Home Care Services

As of January 1, 2005, providers of blood clotting factor are reimbursed by Medicare under Part B according to Section 1847A of the Act at 106 percent of the Average Sales Price (ASP) for the billing and payment code (HCPCS code). Section 303(e)(1) of the MMA created a new separate payment to providers of blood clotting factor for items and services related to furnishing blood clotting factor to Medicare beneficiaries. CMS set the separate payment rate at $0.14 per unit after reviewing comments from the Hemophilia Coalition, comments from patient groups, and a study by the Lewin Group analyzing Coalition members' costs of providing these items and services. As a result, the total Medicare Part B reimbursement for blood clotting factor is 106 percent of the ASP plus $0.14 per unit.

---

[7] J.M. Soucie et al, "Home Based Infusion Therapy and Hospitalization for Bleeding Complications," *Haemophilia*, Volume 7, 198-206.

[8] Alan Heaton and Wallace Wadd, "Combination Approach Crucial for Chronic Illness," *Managed Healthcare*, November 2000, 39-43.

CAP Should Not Apply to Drugs and Biologicals Administered Outside a Physician's Office

As stated previously, hemophilia is a disease primarily treated at home, and blood clotting factor is rarely administered in the physician office. Medicare Part B coverage of blood clotting factors administered in the home is explicitly mandated by Section 1861(s)(2)(I) of the Act, which provides coverage for blood clotting factors "for hemophilia patients competent to use such factors to control bleeding without medical or other supervision, and items related to the administration of such factors..."

While blood clotting factors do fall within the broad universe of potential competitively biddable drugs and biologicals according to the definition in Section 1847B(a)(2)(A), the Hemophilia Coalition believes that under the rest of the statutory provisions of Section 1847B, the CAP program must be limited to include only drugs and biologicals administered incident to a physician's service, and therefore should not include blood clotting factors provided to hemophilia patients for use in the home. The following specific statutory provisions clearly point to this conclusion:

- Section 1847B(a)(1)(A)(ii) and (iii) requires the Secretary to implement a competitive acquisition program under which *"**each physician is given the opportunity annually to elect** to obtain drugs and biologicals under the program, rather than under section 1847A,"* and *"each **physician who elects to obtain drugs and biologicals under the program** makes an annual selection under paragraph (5) of the contractor through which **drugs and biologicals will be acquired and delivered to the physician under this part.**"*
- Section 1847B(a)(3)(A) provides that, "*With respect to competitively biddable drugs and biologicals which are supplied under the program in an area and which are prescribed by a **physician who has elected this section to apply**....(iii) the payment under this section (and related amounts of any applicable deductible and coinsurance) for such drugs and biologicals—(I) shall be made only to such contractor; and (II) **shall be conditioned upon the administration of such drugs and biologicals.**"*
- Section 1847B(a)(4) states that, *"Payment may not be made under this part for competitively biddable drugs and biologicals prescribed **by a physician who has elected this section to apply** within a category and a competitive acquisition area with respect to which the program applies unless—(A) the drugs or biologicals are supplied by a contractor with a contract under this section for such category of drugs and biological and area; and (B) **the physician has elected such a contractor** under paragraph (5) for such category and area."*
- Section 1847B(a)(5)(C) defines selecting physician: *"For purposes of this section, the term **'selecting physician' means**, with respect to a contractor and category and competitive acquisition area, **a physician who has elected this section to apply** and has selected to apply under this section such contractor for such category and area."*[*]

[*] Emphasis added.

The above statutory provisions clearly relate to physicians electing to obtain drugs and biologicals through the CAP for administration in their offices. In the Preamble to the Proposed Rule, CMS makes a similar observation:

> "Section 1847B of the Act describes a program that will permit physicians to elect to obtain drugs from contractors rather than purchasing and billing for those drugs themselves. The statute, therefore, most closely describes a system for the provision of and the payment for drugs provided incident to a physician's service. For example, the mechanisms described in the statue include the following:
>
> - Only physicians are expressly given an opportunity to elect to participate in the CAP.
> - The second sentence of sections 1847B(a)(1)(A) of the Act explicitly indicates that section 1847B shall not apply in te case of a physician who elects section 1847A of the Act to apply.
> - Physicians who elect to obtain drugs under the CAP make an annual selection of the vendor through which drugs will be acquired and delivered to the physician under Part B.
> - Section 1847B(a)(3)(A) of the Act specifically applies the CAP to drugs and biologicals that are prescribed by a physician to has elected the CAP to apply.
> - Payment for drugs furnished under the CAP is conditioned upon drug administration.
> - The submission of information that will be used by the vendor for collection of cost sharing applies to physicians.
> - The primary site for delivery of drugs furnished under the CAP is the physician's office.
> - The statute requires the Secretary to make available to physicians on an ongoing basis a list of CAP vendors.
> - The statute explicitly defines a 'selecting physician' to be one who has elected the CAP program to apply."[9]

Later in the Preamble, CMS states, "Given our concerns about the clear direction of the statute that the election to participate in this program rests with physicians, we do not believe it is possible to include drugs other than those administered as incident to a physician's service as part of this program."[10] CMS specifically asks for comments on this point. The Hemophilia Coalition agrees with CMS' interpretation that these provisions limit the drugs and biologicals that can be included in the CAP to those that are administered in a physician's office. Accordingly, the Coalition does not believe the statute allows for inclusion of blood clotting factor furnished and administered outside a physician's office in the CAP. The statute provides no alternative mechanism by which CAP may apply other than the physician election process. It would not be appropriate for a physician to determine how hemophilia homecare providers would be paid by Medicare through his or her election to participate in the CAP. Furthermore, payment under the

[9] Proposed Rule, pp. 20-21.
[10] Proposed Rule, p. 23.

CAP is conditioned on administration of the drug or biological. CMS has proposed that payment under the CAP to the vendor for the drug or biological cannot be made until the physician has submitted a claim for the administration of the drug or biological and this claim can be matched to the vendor's claim in CMS' claims processing system.[11] This statutory condition and CMS' proposed implementation of it are unworkable for blood clotting factor provided by hemophilia homecare providers for infusion in the home because there would be no administration claim submitted to CMS.

Blood Clotting Factor Should Be Excluded from the CAP When Administered in a Physician Office

The Hemophilia Coalition believes CMS should use the authority granted in Section 1847B(a)(1)(D) of the Act to exclude blood clotting factor altogether from the Competitive Acquisition Program. This provision states:

"(D) EXCLUSION AUTHORITY.—The Secretary may exclude competitively biddable drugs and biologicals (including a class of such drugs and biologicals) from the competitive bidding system under this section if the application of competitive bidding to such drugs or biologicals –

(i) is not likely to result in significant savings; or

(ii) is likely to have an adverse impact on access to such drugs or biologicals."

The Coalition urges CMS to use this authority to exclude blood clotting factor from the CAP even in the rare instances when it is administered incident to a physician's service because it is not likely to result in significant savings to the Medicare program. The vast majority of blood clotting factor units are infused outside the physician office. Furthermore, according to the GAO, there are only 1,100 Medicare beneficiaries with hemophilia in the United States. Given the extremely small Medicare hemophilia population and the infrequency of blood clotting factor administrations in the physician's office, potential savings to Medicare from including clotting factor in the CAP, if any, would not be significant.

In cases when it may be necessary for a physician to administer blood clotting factor in the office, the statute provides an alternative mechanism by which physicians can obtain and be reimbursed for these therapies. Physicians would continue to have ability to purchase clotting factor, bill Medicare, and receive payment under Section 1847A of the Act at 106 percent of the Average Sales Price (ASP).

Conclusion

The statute governing implementation of the CAP clearly limits drugs and biologicals that can be included in the program to those that are administered incident to a physician's services. Because blood clotting factor is rarely infused in a physician's

[11] Proposed Rule, p. 50.

office, the Hemophilia Coalition believes it is unnecessary and inappropriate to include these therapies in the CAP. Furthermore, the Coalition urges CMS to use the authority granted in Section 1847B(a)(1)(D) to exclude blood clotting factor from the CAP when administered in a physician's office on the basis that its inclusion is not likely to result in significant savings to the Medicare program.

The Hemophilia Coalition appreciates this opportunity to provide comments on the Proposed Rule for the Competitive Acquisition of Part B Drugs and Biologics in the Medicare program. We look forward to working collaboratively with CMS in the future to ensure that Medicare hemophilia patients continue to have access to quality hemophilia care in their homes.

Sincerely,

Dave Golding
Senior Vice President, Specialty Pharmacy Services
Caremark Inc.

Paul F. McConnell
President and Chief Executive Officer
Curative Health Services/Critical Care Systems, Inc.

Kyle Callahan
President
Hemophilia Health Services, Inc.

APR 26 2005

BERLEX

April 25, 2005

Mark McClellan, MD, Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1325-P
Room 445-6
Hubert H. Humphrey Building
200 Independence Ave SW
Washington, DC 20201

Jay Schafer, RPh
Director, Government Affairs
6 West Belt
Wayne, NJ 07470
Telephone: (973) 305-5471
Fax: (973) 305-4440

RE: CMS-1325-P (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B)

Dear Administrator McClellan, MD, Ph.D.:

Berlex Laboratories appreciates the opportunity to comment on CMS-1325-P Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B as published in the Federal Register on March 4, 2005.[1]

Berlex Laboratories, the U.S. affiliate of Schering AG Germany, is a pharmaceutical company producing, developing, and marketing specialized medicines in the areas of female healthcare, oncology, central nervous system disorders, and diagnostic imaging. For the past twenty-five years, Berlex has worked to make important treatments available to Medicare beneficiaries.

Our comments regarding CMS-1325-P Medicare Program; Competitive Acquisition of Outpatient Drugs Under Part B, referred to in this comment letter as "Proposed Rule" center around five key areas:

- CMS should ensure that Medicare beneficiaries retain access to the most appropriate drug or biologic specific to the beneficiaries' unique clinical condition and treatment regimen.

[1] 70 Fed. Reg. 10745.

- Due to the uniqueness of certain classes of drugs, certain drugs and biologics should be excluded from the CAP.
- We encourage CMS to reevaluate the CAP vendor bidding mechanism in order to ensure that the pricing of drugs and biologics remain fluid under the CAP. Additionally, we discourage CMS from publishing proprietary contracting and pricing data to the general public.
- We encourage CMS to implement the program in a concise manner and ensure that providers do not experience any undue hardship in participating.
- We applaud CMS for recognizing the education needs of both the provider community and more importantly, the Medicare beneficiary.

I. Beneficiary Access to Drugs and Biologics Furnished Under CAP

Concerns regarding beneficiary access to drugs and biologics furnished under CAP are the most critical issue to consider during implementation of CAP. The Proposed Rule did not adequately address how CMS will ensure that beneficiaries will have access to the best therapeutic option for their treatment. The comments in this section will focus on how CMS can continue to ensure that Medicare beneficiaries receive quality care.

A. Clarification of Coverage for Single-Source Drugs with Unique NDCs

Comments in this section are in response to Overview of the CAP

Statute § 414.905 (d) states that "in the case of a multiple source drug, the Secretary shall conduct such competition among entities for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area."[2] In the Proposed Rule, it is proposed that selected CAP vendors will not be required to provide every National Drug Code associated with a Healthcare Common Procedure Coding System (HCPCS) code[3].

When two products utilize the same HCPCS code, it does not necessarily infer that the products are therapeutically equivalent. Instead, drugs are historically grouped by HCPCS in order to simplify provider billing and payer payment processing. If CAP vendors are only required to provide one drug per HCPCS code, access to the most appropriate brand for the beneficiary would be jeopardized. Each brand of a product may have a unique effect on the patient, creating concerns about efficacy, allergic reactions, antibody development and overall response to therapy.

Additionally, CMS should clarify the intent of Congress, as Statute § 414.905 mandated that at least one drug in a HCPCS code should be offered, the statute does not grant CMS the authority to interfere with the existing relationship between CAP vendors and manufacturers.[4] Although the "furnish as written" provision addressed the issue above,

---

[2] SSA § 1847B(b)(1).
[3] 70 Fed. Reg. 10751.
[4] Id. at 10759.

physicians would have the burden of purchasing the product from another source and bill Medicare under the current ASP methodology. **Therefore, we request CMS require that CAP vendors provide multiple NDCs that are billed under one HCPS code. This practice would eliminate access problems for Medicare beneficiaries who may be unable to tolerate the CAP vendor selected product.**

B. *The Creation of Formularies Under the CAP*
Comments in this section are non-specific to any section of the Proposed Rule but are in response to the ongoing discussions regarding CAP formularies.

Potential CAP vendors have urged CMS to grant them authority to construct formularies under CAP[5]. The creation of these formularies directly conflicts with the statute and as well as Congress' intent for implementing CAP. At a recent briefing of the House Ways and Means Committee members publicly commented that formularies are not permitted by MMA.

The implementation of formularies is not in the best interest of Medicare beneficiaries, as this would create access issues. **Therefore, we urge CMS specifically state that formularies will not be allowed under CAP, as the creation of formularies is in direct contradiction to the Statute and would create access issues for Medicare beneficiaries.**

C. *CMS Should Issue Additional Clarification Regarding Product Selection and Off Label Utilization*
Comments in this section are non-specific to any section of the Proposed Rule but are in response to the ongoing discussions regarding coverage of drugs and biologics under CAP.

Medical decision making is the sole responsibility of the healthcare provider. CAP vendors should not have any discretion or interference with this decision making. Simply, vendors should only serve as the conduit to the drug and dispense the specific NDC as ordered by the physician.

Additionally, CAP is not intended to modify the existing coverage process for drugs and biologics. Medicare's current polices for off-label utilization of drugs and biologics ensure beneficiary access to critical therapies. This practice creates improved standards of care and provides the beneficiary with timely access to innovative therapies. Under these policies, Medicare Contractors have the flexibility to provide coverage of off-label uses. Under the current system, coverage is available when supported by acceptance in selected drug compendia, supported by clinical research as published in select peer-reviewed clinical journals, or where the Carrier has determined the use to be generally medically accepted, safe and effective for a particular use.[6]

---

[5] "CAP Vendors Given Leverage Over Generics, Little Power for Single-Source Drug Prices," Inside Washington Publisher's Inside CMS, Vol.8, No. 5. March 10, 2005.
[6] Medicare Policy Manual. CMS Publication 100-02, §50.4.5.

The current policy allows physician the opportunity to exercise their best clinical judgement in choosing the most appropriate therapy. **In order to maintain the clinical decision making authority in the hands of the most qualified person, we encourage CMS to issue guidance in the Final Rule that reiterates coverage for off-label oncolytics and ensures that the physician, not the CAP vendor, is responsible for treatment decision making.**

D. *CMS Should Create a Clear Exception Process to Ensure that Beneficiaries Maintain Access to Drugs and Biologics*
Comments in this section are in response to Claims Processing Overview

In the Proposed Rule, CMS acknowledges that there may be unique situations when medical necessity requires that a specific formulation of a drug be dispensed to the patient. In this case, CMS proposes to allow the physician to purchase the drugs from another source and be reimbursed by Medicare under the ASP methodology. [7]

While we commend CMS for including this in the Proposed Rule, we are concerned that the increased administrative burden of purchasing the drug and obtaining reimbursement could result in a loss for the practice. Because the patient's clinical condition a particular drug may be required. If the CAP Vendor is not able to supply the particular product, the physician must take the financial responsibility to buy the drug out of their own practice expense and then file for reimbursement for Medicare.

Since the implementation of ASP, there are examples of drugs and biologics that are reimbursed at less than their wholesale acquisition cost (WAC). Therefore, it is likely that the physician would purchase the product at WAC and then be at a loss when the payment is received. The financial risk a physician must incur could potentially effect beneficiary access to certain products.

In order to protect beneficiary access to drugs and biologics, we request CMS implement the Furnish as Written policies but also create provisions to protect physicians from a financial loss in the event they must purchase the drug. Additionally, we encourage CMS provide a specific, detailed exception process where the CAP vendor is required to provide the drug even if it is not initially available from the CAP vendor.

E. *CMS Should Mandate CAP Vendors Provide New Products Upon FDA Approval*
Comments in this section are non-specific to any section of the Proposed Rule but are of concern to Berlex Laboratories.

In the Proposed Rule, CMS proposes to use a composite bid to evaluate bids received from CAP vendors. The composite bid will be weighted based on 2004 utilization data for particular HCPCS code.[8] Noticeably absent from this section of the Proposed Rule is

[7] Id. at 10755.
[8] Id. at 10762.

any indication on how CMS and CAP Vendors will account for drugs billed under the not otherwise classified (NOC) HCPCS codes.

Due to the delays of up to eighteen months for new products to obtain a unique HCPCS codes, the data contained in the bid will not be reflected accurately. Additionally, CMS provides no indication if they will require CAP vendors to provide new products upon FDA approval. Since vendors will be chosen based on the comparison of the composite bid to the 106% of the weighted ASP for the drug category, there is no incentive for CAP vendors to include newly approved products under the CAP.

Unless CAP vendors are required to provide products billed under the NOC codes and any recently FDA approved products, Medicare beneficiaries will not be able to access new, potentially life-saving drugs. **In anticipation, we suggest that CMS provide guidance to CAP vendors on how to account for NOC drugs in their composite bid. Additionally, we request that CMS create provisions that require CAP vendors to provide new, FDA approved drugs in a timely manner, so that Medicare beneficiary access is not compromised.**

II. Consideration to Exclude Certain Drugs and Biologics Under CAP

Congress has excluded certain, unique products from CAP. Although in the Proposed Rule, these products are not excluded from participation.[9] In addition to these statutory exclusions, we feel that it is not appropriate to include certain drugs under the CAP Program, as to do so will create additional access issues.

A. *CMS Should Exclude Contrast Agents from CAP*

Comments in this section are in response to Overview of the CAP

Contrast drugs represent a distinct category of drugs that should be phased in or excluded from competitive acquisition. These drugs are used only in diagnostic imaging tests, such as x-ray, CT, MRI and echocardiography. The recent revisions on January 1, 2005, in coding and reimbursement for low osmolar contrast drugs and the impending changes on July 1, 2005 in coding and reimbursement to describe other contrast agent drugs have created a new fluid reimbursement environment. The addition of these drugs under CAP will not likely result in cost savings for the Medicare program.

Contrast drugs could be represented in several categories, such as LOCM, HOCM, MR contrast agents, and echocardiography contrast agents or may better be represented in several categories such as outlined in the new HCPCS coding matrix. If these drugs are to be included in competitive acquisition at all, they must first be placed in an appropriate

[9] Id. at 10749.

category. Multiple categories would be needed as the features of these products vary widely.

MMA also authorizes CMS to exclude from competitive acquisition a drug or class of drugs if the application of competitive acquisition to the drug(s) is not likely to result in significant savings or it is likely to have an adverse impact of access to such drugs.[10] This classification of many contrast drugs under one HCPCS code has the effect of lowering the ASP and thus achieving cost savings. The marginal savings from competitive acquisition, relative to the newly determined ASP, will not be significant. Berlex urges CMS to exclude contrast drugs because the recently established ASP pricing for contrast drugs is based on the averaging of a number of different manufacturers pricing into the ASP. **CMS should consider excluding contrast drugs from competitive acquisition, as contrast drugs will not achieve significant savings, and access could be restricted. If CMS is compelled to include contrast drugs in competitive acquisition that CMS phase in contrast agents into competitive bidding in 2007 or 2008.**

B. *CMS Should Exclude Orphan Drugs from CAP*
Comments in this section are in response to Overview of the CAP

A rare disease is one that afflicts fewer than 200,000 Americans. There are an estimated 6,000 rare diseases that cumulatively affect over 25 million U.S. citizens.[11] The Orphan Drug Act, passed in 1983, was designed to offer incentives to drug manufacturers to promote development of new drugs, biologics, and medical foods for people with rare diseases. Before 1983, new innovative products were not as readily available as research and development costs outweighed the sales potential to small populations of patients.

Beneficiaries who require therapy with FDA-approved orphan drugs are often temporarily or permanently denied access to appropriate therapies because low demand and/or high cost of orphan products. CMS has recognized that orphan drugs present an access challenge by creating an exception in reimbursement for orphan drugs under the hospital outpatient payment system[12]. As discussed above, MMA authorizes CMS to exclude from competitive acquisition a drug or class of drugs if the application of competitive acquisition to the drug(s) is not likely to result in significant savings or it is likely to have an adverse impact of access to such drugs.[13]

We commend CMS for many of the provisions regarding payment for drugs and biologics that have been implemented within other sites of service. The uniqueness and unfamiliarity of orphan drugs creates an opportunity for CMS to continue to ensure access to critical therapies. **Therefore, we encourage CMS to exclude Orphan Drugs from the CAP as the vendor may not be able to adequately provide orphan products in a timely manner, and the likelihood that CMS will not see any significant savings by providing orphan drugs under the CAP.**

---

[10] SSA § 1847B(b)(1) and 70 Fed. Reg. 10749.
[11] National Organization for Rare Diseases, available at http://www.rarediseases.org.
[12] 69 Fed. Reg. 65807. Nov. 15, 2004
[13] SSA § 1847B(b)(1) and 70 Fed. Reg. 10749.

III. CAP Vendor Selection Process and Bid Concerns

The Proposed Rule raises questions regarding the use of the composite ASP in the bidding process. In many cases, ASP can fluctuate as much as 10 percent per quarter as purchase price changes. Due to the fluidity of ASP, we are concerned about the use of ASP rates in the selection process.

A. *Under the Composite Bid System, There is not Any Mechanism to Account for Price Increases*
Comments in this section are in response to Claims Processing Overview

In the Proposed Rule, CMS did not specify which quarterly ASP it plans to use to compare composite bids. Additionally, CMS has not provided a mechanism to make projections on the effect on ASP when a product has experienced a price adjustment. If CMS used third quarter 2005 ASP payment rates to evaluate a potential bid, the current actual price a CAP vendor may purchase the product for may not correspond with third quarter ASP. In determining the 2005 payment rates for separately billable drugs furnished under dialysis facilities, CMS used the Producer Price Index in order to update prices from 2003 to 2005.[14]

While we commend CMS for creating a mechanism to update prices, the frequency of the update is inadequate. **We encourage CMS to develop a mechanism to allow CAP Vendors to account for manufacturer price adjustments in a timely manner so that CAP Vendors are not penalized in the event that the composite ASP exceeds current ASP.**

B. *Release of Proprietary Data Regarding Contracting and Pricing*
Comments in this section are in response to CAP Bidding Process – Evaluation and Selection

In the Proposed Rule, CMS is requiring that vendors must disclose their reasonable, net acquisition costs annually.[15] As mentioned above, not only is the timeliness of the updates inadequate in response to market changes, the disclosure process is of concern to Berlex. **We request that CMS treat pricing and acquisition cost data as proprietary and confidential trade secrets. Specifically, the data should be protected so that the identity of a specific manufacturer or wholesaler is not disclosed.**

C. *CMS Should Provide Clarification that Acquisition Cost to CAP Vendors Should Not Be Included in ASP Calculations*
Comments in this section are in response to CAP Bidding Process – Evaluation and Selection

The Proposed Rule failed to address whether the price paid by the CAP vendor would be included in ASP calculations. It is our belief that the intent of the authors of the Statute is

[14] 69 Fed. Reg. Nov 15, 2004 66236, 66231.
[15] 70 Fed. Reg. 10764.

that CAP prices should not be subject to ASP calculation. Congress' intent was to keep CAP pricing separate from ASP calculation. **Therefore, we encourage CMS to publish guidance that explicitly excludes CAP pricing from ASP calculations as intended by Congress.**

IV. Implementation Concerns of Providers and Beneficiaries Under CAP

It is evident in the Proposed Rule that CMS recognizes the administrative hassles of the CAP for both Physicians and Medicare beneficiaries. We applaud CMS for providing extensive education initiatives to both groups.[16] However, it is important that CMS create a mechanism to address the concerns of Provider and Beneficiaries

A. *CMS Should Address Physician Concerns Regarding CAP*

Comments in this section are in response to Claims Processing Overview and Dispute Resolution

In the Proposed Rule, CMS states that the clerical and inventory resources associated with participation in the CAP exceed the clerical and inventory resources associated with buying and billing for drugs under the ASP system.[17] Many of the physician requirements for participation in the CAP as proposed will create additional work for physicians and their staff. Therefore we suggest CMS create a working group of providers to provide input on ways CMS can minimize the administrative burden of participation.

Based on the information outlined in the Proposed Rule, there are several additional steps in billing for drugs and biologics that CAP participating physicians must complete that non-participating physicians do not. For example, the frequent audits as suggested in the Proposed Rule create additional administrative burden to the physician. Additionally, the documentation associated with ordering the drugs from the CAP Vendor is cumbersome, especially when the patient is unable to receive the drug as scheduled. In this case the physician must notify the vendor, work out arrangements to use the drug on another Medicare beneficiary, document in inventory records and on future orders.[18]

We are pleased that CMS is considering a process of dispute resolution. However, the dispute resolution as proposed, does not sufficiently outline the process. In the event that the CAP vendor's claim can not be paid when the physician's administration claim is denied, CMS has commented that the physician will be responsible for appealing the claim.[19] In many cases the cost of appealing the claim may be greater than the payment for administration procedure. Additionally, if the claim for administration charges were

---

[16] Id. at 10767.
[17] Id. at 10755.
[18] Id. at 10756.
[19] Id. at 10758.

less than $100, then the claim would not meet the requirements of an Administrative Law Judge hearing, preventing successful resolution of the claim.[20]

While many of the implementation steps for participating in the CAP have not yet been outlined, we recommend that CMS explore ways to minimize the administrative burden for participating physicians. In the event that CMS is not able to minimize the burden, CMS should reconsider compensation for CAP physicians.[21] Additionally, CMS should clarify the dispute process so that both vendors and physicians are protected.

B. CMS Should Continue to Develop Provider and Beneficiary Education
Comments in this section are in response to Vendor or Physician Education and Beneficiary Education

We are pleased that CMS has created requirements to educate all of the key stakeholders involved in the CAP.[22] We encourage CMS to continue to implement these measures and explore additional options for educating key stakeholders.

Conclusion

Berlex appreciates the opportunity to provide comment to the Proposed Rule. Additionally we commend CMS for considering key stakeholder comments on this important Proposed Rule. In summary we recommend that CMS consider the following concerns when drafting the Final Rule:

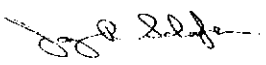
- Ensure that Medicare beneficiaries retain access to the most appropriate drug or biologic specific to the beneficiaries' unique clinical condition and treatment regimen.
- Due to the uniqueness of certain classes of drugs, Imaging Agents and Orphan Drugs should be excluded from the CAP.
- We encourage CMS to reevaluate the bidding mechanism in order to ensure that pricing of drugs and biologics remains fluid under the CAP. Additionally, we discourage CMS from publishing proprietary data such as contracting and pricing to the general public.
- We encourage CMS to implement the program in a concise manner and ensure that providers and beneficiaries do not experience any undue hardship by participating.
- We encourage CMS to continue to implement educational programs that address the needs of both the provider community and the Medicare beneficiary.

---

[20] 42 CFR § 405.1006.
[21] 70 Fed. Reg. at 10755.
[22] Id. at 10766 and 10767.

If you have any questions about our comments, please contact Jay Schafer at 973-305-5471. Thank you for your consideration of the above comments.

Sincerely,



Jay Schafer, RPh
Director, Government Affairs

60.

PPTA

Plasma Protein Therapeutics Association

APR 26 2005

April 26, 2005

BY HAND DELIVERY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1325-P (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B)

Dear Administrator McClellan:

The Plasma Protein Therapeutics Association (PPTA) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding the competitive acquisition program (CAP) for outpatient drugs and biologicals under Part B, published in the Federal Register on March 4, 2005 (the Proposed Rule).1 PPTA is the association that represents the commercial producers of plasma-derived and recombinant analog therapies (collectively, "plasma protein therapies"). These therapies are used by millions of people to treat a variety of diseases and serious medical conditions. PPTA members produce over 80% of the plasma therapies for the United States market and more than 60% worldwide. Some of the critical therapies produced by PPTA members include: blood clotting factors for people with hemophilia, intravenous immune globulin (IVIG) used to prevent infections in people with immune deficiencies and other serious conditions, and alpha-1 proteinase inhibitors used to treat people with alpha-1-antitrypsin deficiency, also known as genetic emphysema.

PPTA shares Congress' recognition that the CAP program is not appropriate for all drugs and biologicals. In particular we believe that if blood clotting factors and alpha-1 proteinase inhibitors are included in the program, it will have a significant adverse impact on individuals with hemophilia and other bleeding disorders and with alpha-1 antitrypsin deficiency because the CAP Program requires contractors to furnish just one product per billing and payment code within each category. Given the individual differences in clinical response to biological agents, patients reliant on plasma protein therapies to replace critical proteins that their bodies do not make naturally, these treatments do not lend themselves to a one-size-fits-all approach. Though many

1 70 Fed. Reg. 10745 (Mar. 4, 2005).

147 Old Solomons Island Road · Suite 100 · Annapolis, MD 21401 USA
tel: 202.789.3100 · 410.263.8296 · fax: 410.263.2298 · e-mail: ppta@pptaglobal.org · www.pptaglobal.org
PPTA Offices in Washington · Annapolis · Brussels · Tokyo

patients may respond to a particular manufacturer's product, other patients with the same diagnosis do not.

PPTA believes it is absolutely imperative that patients be allowed to access the most effective treatment for their individual condition. Currently, there are multiple products bundled within each of the five Healthcare Common Procedure Coding System (HCPCS) blood clotting factor codes, and all three alpha-1 products are packaged within a single HCPCS code, even though none of the products are interchangeable. As mentioned above, because CAP requires contractors to furnish just one product in a HCPCS code, a contractor may not offer the product that is most beneficial to an individual. While PPTA supports inclusion of a fail-safe mechanism for physicians to obtain the most therapeutically beneficial brand of product for their patient, without seeing details of the design (including the added administrative burden for physicians), PPTA asserts that the "furnish as written" provision in the Proposed Rule provides insufficient assurance that the patient would be able to get the brand they need in a timely or cost effective manner. In addition, if the physician exercised her or his right to obtain the best product for their patient, the Proposed Rule states that CMS anticipates that the carrier would "at times" conduct post payment reviews and ultimately determine if the medical necessity requirement was met. Given the prospect of facing such scrutiny and administrative hurdle, we remain skeptical that the "furnish as written" provision is a viable option for assuring access to the full range of plasma protein therapies. Furthermore, while the "furnish as written" stipulation is mentioned in the preamble of the Proposed Rule, it does not explicitly appear in the proposed regulations text under § 414.906(c)(2).

In addition to an exclusion based on access concerns, blood clotting factor should also be excluded from the CAP on the grounds that it is primarily administered in the home, not by a physician in the physician's office. Many of the mechanisms laid out in the Proposed Rule for obtaining product, emergency replacement situations, the appeals process and payment are designed for physician administered drugs and will not work effectively for patients who get their blood clotting factor delivered to their home through specialty pharmacies, homecare companies or hemophilia treatment centers (HTCs). The Proposed Rule expressly states that CAP vendors would deliver drugs directly to physicians in their offices. In addition, the trigger for vendor payment in the CAP Program is the physician claim for drug administration. For people with hemophilia who self-infuse in the home, there would be no physician to submit a claim upon administration and therefore vendors would not be able to get reimbursed by Medicare or to charge the beneficiary or a third party insurer for any applicable deductible or coinsurance.

For the above reasons which are discussed in more detail below, PPTA urges CMS to recommend that Secretary Leavitt exercise his authority to exclude all plasma-derived and recombinant analog therapies including blood clotting factors and alpha-1 proteinase inhibitors (and intravenous immune globulin, as required by statute) from the

CAP Program. We offer specific comments on the design of the CAP in the unfortunate circumstance that CMS decides not to exclude blood clotting factors and alpha-1 proteinase inhibitors. In this case, PPTA agrees that with CMS that it makes sense from a logistical and financial standpoint to phase in the CAP program beginning with drugs typically administered by a single physician specialty such as oncologists. We concur that focusing efforts on one specialty with more homogenous set of issues and concerns makes sense. Furthermore, as oncology drugs constitute a large portion of the Part B market and the largest portion of expenditures for physician administered drugs under Medicare, it makes sense to begin there because as CMS points out, under this scenario it will be possible to begin to realize much of the benefit potential of the CAP program.

In addition, the following issues are essential to make CAP a legitimate option for patients and providers. First and foremost, the CAP program must offer all physicians broad access to appropriate biologicals including all plasma protein therapies. PPTA strongly recommends that at a minimum, CMS require vendors to bid on at least one NDC for each single source drug and biological, even when the therapies are billed using the same HCPCS. Also, physicians must have the freedom to employ the resupply and "furnish as written" options to provide their patients with critical drugs and biologicals. Furthermore, physicians, not CAP vendors, must make medical decisions regarding the appropriate plasma protein therapies for their patients. PPTA recommends that CMS make modifications to help ensure that the CAP program does not impose excessive burdens on participating physicians. Physicians' clerical and inventory obligations must be kept to a minimum to help ensure that the CAP is a practical option. Finally, it is essential to limit participation to quality vendors. Because timely and reliable delivery of drugs and biologicals is central to the CAP's operation, we recommend that CMS make bidders' distribution systems a priority in the agency's quality review. It is critical that vendors also demonstrate their ability to maintain the integrity of plasma protein therapies which have very specific handling requirements by meeting FDA good manufacturing processes (GMP) regulations for drug distributors.

A. Categories of Drugs To Be Included Under the CAP

1. Statutory and Regulatory Exclusions

PPTA notes that Congress has excluded certain products from CAP and the Proposed Rule appears not to adhere to these exclusions. For example, the Proposed Rule seems to suggest that intravenous immune globulin (IVIG) is subject to CAP when it notes that blood and products (not including IVIG) are excluded.2 However, SSA § 1842(o)(1)(E)(ii) states that "in 2005 and subsequent years, the amount of payment provided under section 1847A" (i.e., ASP plus 6%) is how Medicare pays physicians and supplier that furnish IVIG. The Conference Report to the MMA confirms that IVIG is

---

2 Id. at 10749.

excluded from CAP – "[c]ompetitively biddable drugs and biologicals exclude . . . IVIG products and blood products."3 PPTA believes that CMS needs to identify the exclusion of these therapies from CAP explicitly in the final rule.

In addition to these statutory exclusions, Congress recognized that some drugs and biologicals may not be appropriate to include in the CAP because patient access to them likely would suffer under competitive bidding. Specifically, SSA § 1847B(a)(1)(D) authorizes the exclusion from the CAP of any drugs and biologicals for which competitive bidding is not likely to achieve significant cost savings or is likely to have an adverse impact on access. PPTA urges CMS to exercise its exclusion authority to protect access to blood clotting factors and alpha-1 proteinase inhibitors. As described above, multiple brands of clotting factor are included within each of the five HCPCS codes for blood clotting factors and all three alpha-1 proteinase inhibitor (A1PI) therapies are bundled within the code for A1PI, yet the brands are not therapeutically equivalent and each has a unique clinical effect on the patient. Because of clinical differences in efficacy, allergic reactions, and response times, it is critical that each patient receive the specific brand that is best suited for his or her condition. Without a mandate to carry at least one NDC for each single source product (meaning each brand), we are doubtful that a CAP vendor would provide the brand patients need. This is particularly true because the small number of Medicare beneficiaries who use each of these therapies. Thus, each patient's access to the appropriate clotting factor or alpha-1 proteinase inhibitor would be protected best by excluding these products from the CAP.4

CMS states in the Proposed Rule that they do not intend to rely "at this time" on the Secretary's authority under 1847(a)(1)(D) of the Act to exclude competitively biddable drugs and biologicals from the CAP on the grounds that including those drugs or biologicals would not result in significant savings or would have an adverse impact on access. PPTA contends that Congress gave the Secretary exclusionary authority to use for exceptional cases just like blood clotting factors, alpha-1 proteinase inhibitors and intravenous immune globulin (which is already exempt by statute). If CAP vendors are required to supply only one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area, then there will most certainly be an access problem for the small, fragile patient populations who require a particular brand of clotting factor or alpha-1 proteinase inhibitor not offered by their physician's vendor. This could be especially true if a patient is under the care of a general practitioner who is not well versed in their rare disease and therefore chooses a vendor who does not offer a broad range of plasma protein therapies.

---

3 H.R. Conf. Rep. No. 108-391, at 593.

4 Given that clotting factor can be covered under SSA § 1861(s)(2)(I), rather than as an "incident to" drug, and that CMS is focusing on "incident to" drugs for CAP, the alternate coverage basis for clotting factor provides another reason to exclude it from CAP.

PPTA
Plasma Protein Therapeutics Association

2. Intent of the Program

In addition to an exclusion based on access concerns, blood clotting factor should also be excluded from the CAP on the grounds that they are primarily administered in the home, not by a physician in the physician's office. As stated in the Proposed Rule, "Section 1847B of the Act describes a program that will permit physicians to elect to obtain drugs from contractors rather than purchasing and billing for those drugs themselves." As explained above, PPTA asserts that the statute most closely describes a system for the provision of and the payment for drugs provided incident to a physician's service. For example, the mechanisms described in the statute include the following:

- Only physicians *(and not pharmacies)*, are expressly given an opportunity to elect to participate in the CAP.
- Physicians who elect to obtain drugs under the CAP make an annual selection of the vendor through which drugs will be acquired and delivered to the physician under Part B.
- Payment for drugs furnished under the CAP is conditioned upon drug administration.
- The submission of information that will be used by the vendor for collection of cost sharing applies to physicians.
- The primary site for delivery of drugs furnished under CAP is the physician's office.
- The statute requires the Secretary to make available to physicians on an ongoing basis a list of CAP vendors.

In the vast majority of cases, clotting factors are obtained directly from specialty pharmacies or the equivalent. People with hemophilia or other bleeding disorders then self infuse in their homes. They are able to be more productive members of society because they spend less time in physician office, hospital emergency department and hemophilia treatment center waiting rooms. In addition, compliance with treatment regimens is more realistic for people with hemophilia and other bleeding disorders who are able to infuse in the home. Moreover, home infusion has the potential to save the government the cost of paying for emergency visits, the complications resulting from delayed treatment which lead to other comorbidities, hospitalizations and the need for joint replacements etc. For the particular case of blood clotting factors, the burden of acquiring drugs and collecting coinsurance that CAP aims to eliminate for physicians is already handled by the homecare providers. On this basis we ask that blood clotting factors be exempted from the CAP Program.

B. CAP Program Design Issues - Patient Access to and Choice of Appropriate Therapies

1. Provide Sufficient Therapeutic Options

Patient access to critical therapies under the CAP depends on the amount of choice available to participating physicians. CAP vendors must provide physicians and other Part B providers with the full range of plasma protein therapies currently available on the market to meet their patients' unique needs. We understand that vendors have been urging CMS to grant them authority to construct formularies under the CAP.[5] PPTA asserts that such formulary authority conflicts with the statute as well as Congress' intent in enacting the CAP Program and asks CMS to state affirmatively in the final rule that vendors do not have the authority to construct formularies. CAP formularies are also not in the best interest of providers and of patients who critically need access to a broad range of therapies. It is essential that each patient receive the specific brand that is best suited for him or her. As mentioned above, multiple brands of blood clotting factors and alpha-1 proteinase inhibitors are currently included within a single HCPCS code even though the brands are not therapeutically equivalent and the therapies are recognized as single source biologics. Single source drugs and biologicals[6] including plasma protein therapies are not rated as therapeutic equivalents in the Orange Book and have not otherwise been found to be pharmaceutically equivalent or bioequivalent by the FDA. Each brand has a unique effect on the patient, and efficacy, allergic reactions, development of inhibitors, and response times can vary from patient to patient.

Including single source therapies in the same HCPCS code never was meant to signify that products were interchangeable. Instead, therapies historically were grouped as a means of simplifying provider coding and reimbursement. Requiring each CAP vendor to bid on at least one NDC for each single source drug and biological in a category would ensure Medicare beneficiaries have access to the brand that works best for them. Although the "furnish as written" provision also addresses this issue, physicians would need to purchase the necessary therapy from another source and bill Medicare under the ASP methodology. Requiring vendors to bid on at least on NDC for each single source drug and biological would be much less administratively burdensome and would provide physicians with the true choice that the CAP program promises. It also would help ensure that Medicare beneficiaries have access to the brand most appropriate for them. Accordingly, PPTA requests that CMS renumber proposed § 414.908(e) as § 414.908(f) and insert the following as 42 C.F.R. § 414.908(e):

---

5 "CAP Vendors Given Leverage Over Generics, Little Power for Single-Source Drug Prices," Inside Washington Publisher's Inside CMS, Vol. 8, No. 5 (March 10, 2005).

6 Under the definition applied in SSA § 1847A(c)(6)(D), a single source drug or biological is: (I) a biological or (II) a drug which is not a multiple source drug and which is distributed under a new drug application approved by the Food and Drug Administration. We have included this definition in our proposed regulatory text.

(e) Single Source Drugs and Biologicals. In the case of single source drugs and biologicals, there must be a competition among entities for the acquisition of at least one national drug code for each competitively biddable single source drug or biological within each billing and payment code within each category for each competitive area. For purposes of this paragraph, a single source drug or biological is either a biological or a drug which is not a multiple source drug and is distributed under a new drug application approved by the Food and Drug Administration.

Obligating vendors to provide at least one NDC for each single source drug or biological within each HCPCS code would help to ensure physician choice and patient access to needed plasma protein therapies.

2. Ensure that Physicians, Not CAP Vendors, Make Medical Decisions

It is imperative that the final rule stress that medical decisions should be made by physicians and not by CAP vendors. Rather than second-guessing physician orders and interfering with medical decision-making, vendors should serve as the physician's conduit and pharmacy, dispensing the specific NDCs ordered by the physician from the vendor's list. For example, a patient may need a 55 mg dose of a drug that is available in 10 mg packages. The physician would order six of the 10 mg packages and 5 mg would not be used. CMS should clarify that its standard policy on discarded drugs will be applied in situations such as this when there are drug remnants. It should be the responsibility of the physician and not the vendor to attempt to schedule patients in a manner that minimizes remnant drugs in accordance with the agency's policy on this issue.

In addition, CMS should reiterate that physicians and their local Medicare carriers will be responsible for verifying that a drug or biological is being used consistent with any local coverage determinations (LCDs).[7] CMS should reiterate its statements to the Practicing Physician Advisory Council (PPAC) that "nothing in the CAP program in any way modifies the existing coverage process," and that vendors must supply drugs, whether or not they are ordered for off-label uses.[8]

Medicare's current coverage policies for off-label uses of drugs and biologicals work well to ensure beneficiary access to critical therapies. The practice of medicine constantly evolves through the incorporation of clinical evidence into improved standards of care. Current Medicare coverage policies support this evolution by

---

7 Id.

8 "Competitive Acquisition Vendors Should Pay Drug Returns – CMS Doctor Panel," The Pink Sheet, Mar. 14, 2005, at 25; "CAP Vendors Given Leverage Over Generics, Little Power for Single-Source Drug Prices," Inside Washington Publisher's Inside CMS, Vol. 8, No. 5 (March 10, 2005).

allowing carriers to respond quickly to advances in care and new research thereby reducing beneficiaries' wait for access to innovative therapies. Under these policies, carriers enjoy the flexibility to cover off-label uses of therapies that are listed in selected compendia, supported by clinical research that appears in peer-reviewed medical literature, or are "determined by the carrier to be medically accepted generally as safe and effective for the particular use."9 The current off-label policies also allow physicians to exercise their professional judgment in choosing the best treatment options for their patients. We urge CMS to ensure that the implementation of the CAP will not interfere with this process that works so well. In all cases, physicians, not CAP vendors, must decide what therapy the patient will receive.

3. Least Costly Alternative Policies Should Not Apply Under the CAP

On the other hand, we believe that Medicare carriers' least costly alternative (LCA) policies should not apply under the CAP. Substituting one drug or biological's price for another's is inconsistent in a system where a vendor competitively bids to supply each HCPCS in a given category and the composite bids are capped at 106% of ASP.

In addition, the administrative hurdles make the application of LCA under the CAP inappropriate and impracticable. For example, carriers that apply LCA allow physicians wanting to provide the higher cost drug or biological to their patients to obtain an advanced beneficiary notice (ABN) and collect an amount in excess of the Medicare payment from them. Because a CAP vendor does not see the patient, it will be difficult for the vendor to request an ABN and the physician does not have the same incentive to obtain one. Moreover, many LCA policies contain "grandfathering" clauses for patients using the drug prior to the implementation of the policy. Others make exceptions for patients for whom the therapy is medically necessary. Again, these policies will be difficult to administer under the CAP. Applying LCA policies in a CAP environment is impracticable and unnecessary, and CMS should convey this message to carriers in the final rule.

C. Claims Processing Overview

Congress intended the CAP to provide physicians who administer drugs in their offices or infusion suites with an alternative method of acquiring drugs and biologicals for their patients. It will succeed only if it offers physicians less administrative and financial inconvenience while also ensuring continued patient access to essential therapies. In the Proposed Rule, CMS describes the procedures it intends to use to process claims for drugs and biologicals under the CAP. As CMS finalizes these procedures, PPTA urges the agency to minimize the burden on physicians. We make the following recommendations to make the CAP more attractive for both physicians and patients.

---

9 Medicare Benefit Policy Manual (CMS Pub. 100-02), ch. 15, § 50.4.5.

1. CMS Must Allow Physicians to Use the "Furnish as Written" Option to Provide Their Patients with the Most Appropriate Drug and Biological Therapies

CMS recognizes in the Proposed Rule that physicians may not be able to obtain the specific formulation of a drug or biological that the patient needs from the CAP vendor. As noted earlier, PPTA urges CMS to require vendors bid on at least one NDC for each single source drug and biological. This would still mean that the specific formulation a patient needs might not be available from the CAP vendor. In these cases, CMS proposes to allow physicians to purchase the drugs from another source and to bill Medicare using the ASP methodology.10 PPTA commends CMS for including this proposal, and we strongly urge that it be finalized. We also recommend that CMS allow physicians to exercise this option with as minimal an administrative burden as possible. The design of this provision will either make it workable or make it burdensome enough that the physician would be highly unlikely to exercise the option. In addition, PPTA asks CMS to conduct significant outreach efforts to make physicians aware that the "furnish as written" option is always available if their patient needs a specific brand or formulation of a therapy that is not offered by the vendor.

2. CMS Must Allow Physicians to Use the Resupply Option to Ensure Timely Access to Drugs and Biologicals

Many drug and biological regimens must be administered on precise schedules. For patients receiving these therapies, it is imperative that their physicians are able to provide the right drug at the right time. This can be challenging when changes in a patient's condition require immediate adjustments to the patient's course of treatment. Rather than risking deterioration in their patients' condition while they wait for the CAP vendor to fill their orders, physicians need to be sure that CAP vendors will provide products on a timely basis and that there is an alternative to the regular CAP ordering process to ensure timely access to crucial plasma protein therapies.

We understand that physicians are very concerned about the possibility that CAP vendors will not provide drugs and biologicals on a timely basis. When a patient comes to a physician's office solely for the administration of a product and it is not there, not only is there a delay in the treatment for the beneficiary, but there are costs to both the physician and the beneficiary. The Proposed Rule contains considerable protections for CAP vendors in situations when the physicians are not fulfilling their obligations under CAP. When a physician has concerns, however, such as the failure of the vendor to deliver drugs and biologicals in a timely fashion, the Proposed Rule offers very limited protections. The physician may go through the vendor's grievance process and if there is no satisfactory resolution, the physician can approach the designated carrier.11 PPTA suggests that physicians be given an opportunity to resolve issues such as a

---

10 70 Fed. Reg. at 10755.

11 See 70 Fed. Reg. at 10772 (proposed 42 C.F.R. § 414.916(d)).

vendor's failure to deliver drugs on a timely basis through a mechanism likely to produce resolutions more immediately.

Congress recognized that physicians would not always be able to obtain the drugs their patients need in a timely manner under the CAP. Section 1847B(b)(5) of the SSA requires the Secretary to establish rules that allow physicians to resupply their own inventories with drugs and biologicals acquired under the CAP. CMS proposes to require the physician to demonstrate: (1) the drugs were required immediately; (2) the physician could not have anticipated the need for the drugs; (3) the vendor could not have delivered the drugs in a timely manner; and (4) the drugs were administered in an emergency situation. CMS does not propose a definition of an "emergency situation," but asks for comment on how it should be defined.12 If this term is defined narrowly, the usefulness of the resupply option could be limited severely. For this proposal to effectively protect patient access to drugs and biologicals, CMS must allow physicians the flexibility to meet their patients' needs and prevent dangerous interruptions in care.

PPTA urges CMS to apply an expansive definition of "emergency situation" that recognizes (i) the unpredictable nature of patient care and (ii) that delaying care, rather than using existing inventory resupplied by the CAP vendor, would be contrary to the beneficiary's best interests. Although a physician often can plan a patient's course of treatment far enough in advance to order drugs through the CAP vendor, he or she cannot always plan ahead for the patient's adverse reaction to a drug or change in condition since the last treatment. Providing a therapy to address an adverse reaction or a change in the patient's condition must be included within the definition of emergency situation. Physicians also cannot predict when a scheduled delivery will be delayed. When the patient is in the office, needing treatment, it is unacceptable to delay care by sending the patient home to wait for the CAP order to arrive. Moreover, this is burdensome for beneficiaries when they would incur additional coinsurance by returning on another day or to the extent they have difficulty traveling to and from the provider's office. These situations must also be included within the definition of emergency situation so that the physician is able to provide the therapy the patient needs from his or her own stock and order a replacement from the CAP vendor.

Finally, CMS should allow physicians to request that a CAP vendor provide an advance supply of certain drugs and biologicals (that physicians use only in response to immediate patient needs) from the CAP vendor to treat patients whose needs cannot be predicted. These therapies should be provided at the expense of the CAP vendor. A physician who participates in the CAP and treats primarily Medicare patients may not have his or her own inventory of drugs. Rather than requiring the physician to purchase these drugs and biologicals on his or her own, the physician should be allowed to request them from the CAP vendor at the vendor's expense and submit claims as they are used.

---

12 Proposed 42 C.F.R. § 414.906(e), see also 70 Fed. Reg. at 10755.

3. CMS Must Ensure that the CAP's Clerical and Inventory Burdens on Physicians are Minimal

Although one of the primary purposes of CAP according to the Proposed Rule is to relieve physicians of financial and administrative burdens of the ASP system, our understanding is that many physicians are very concerned about the administrative burdens of participating in the CAP. In the Proposed Rule, CMS states that it does not believe the clerical and inventory resources associated with participating in the CAP exceed the costs of purchasing and billing for drugs under the ASP system.13 We urge CMS to review its proposed requirements and consider input from physicians to ensure that this is true. For example, CMS anticipates that carriers will perform post-payment review when physicians use the resupply or "furnish as written" options.14 Although we understand CMS' concern with monitoring physicians' compliance with the CAP rules, frequent audits would increase the burdens associated with participating in the CAP. Moreover, as discussed above, we firmly believe that more liberal interpretations of these provisions, with less vendor discretion, are warranted and would be beneficial to patients and physicians alike.

Physicians' administrative burdens also may be greater under the CAP than under ASP-based reimbursement because of requirements to maintain a separate electronic or paper inventory for each CAP drug obtained and to file the Medicare claim within 14 days of the date of drug administration.15 They also may be greater when a scheduled treatment is not delivered on time because the physician may be forced to reschedule the patient, particularly if the agency does not define emergency situation in the resupply authority more broadly as we suggest. Similarly, if a patient refuses to receive a scheduled drug infusion, the physician must notify the vendor, work out an arrangement to use the drug for another Medicare beneficiary, and make appropriate notations in the inventory records and on future orders.16 CMS also proposes to require physicians to provide the patient's height and weight on the order, 17 information that is unnecessary because the dose is provided. PPTA thus recommends that CMS remove height and weight from the information required on the physician's order to the CAP vendor.

Under the ASP-based reimbursement system, the physician faces none of these burdens. PPTA urges CMS to do everything possible to minimize the clerical and administrative burdens on participating physicians so that the CAP can be a viable option for all physicians. To the extent the agency is not able to minimize such burdens,

---

13 70 Fed. Reg. at 10755.
14 Id. at 10756.
15 Proposed 42 C.F.R. § 414.908(a)(3).
16 70 Fed. Reg. at 10756.
17 Id.

PPTA recommends that the agency consider making payments to physicians that elect CAP to compensate them for the increased costs of participation in the program.

D. Contracting Process - Quality and Product Integrity Aspects

CMS proposes to "define a set of overall financial and quality standards that would ensure that reputable and experienced vendors are chosen to participate in the CAP."18 PPTA supports this goal, and we agree with CMS that physician confidence in the CAP vendors' reliability and quality is essential to encourage physicians to participate. We also agree with CMS that the CAP vendors must be required to provide "quality products in a timely manner."19 We urge CMS to pay particular attention to prospective vendors' distribution systems because the success of many drug and biological regimens, and the life and health of Medicare beneficiaries, depends on vendors' ability to deliver the right therapies, at the right time, in perfect condition. In addition, PPTA feels the following criteria for vendor selection are essential:

1. Contractors must have the appropriate facilities to ensure product integrity
   - Refrigeration storage requirements (temperature 2-8 degrees C or 36 – 46 F)
   - Freezing must be avoided
   - Must offer protection from extreme exposure to light
2. Contractors must maintain inventory and distribution records in case of a product withdrawal or recall.
3. Contractors must ship product with freeze packs. For those products with room temperature requirements, shipments in hot temperature must be in refrigerated trucks and cold temperature freezing must be avoided.
4. Contractors must have quality standard operating procedures. Once the product is shipped from the manufacturer to the contractor, product liability related to storage and handling transfers to the contractor.

CMS proposes to suspend or terminate a vendor's CAP contract if the vendor falls out of compliance with any of the quality requirements.20 CMS does not explain, however, how physicians will obtain drugs and biologicals when the contract is suspended or terminated. PPTA proposes that physicians be allowed to buy drugs and biologicals and be reimbursed at 106% of ASP so that their patients can continue to receive care.

Conclusion

PPTA appreciates this opportunity to comment on our concerns about the Proposed Rule, and we look forward to working with CMS to protect Medicare beneficiaries'

---

18 70 Fed. Reg. at 10759.
19 Id.
20 Id. at 10758.

PPTA
Plasma Protein Therapeutics Association

access to life-sustaining plasma protein therapies. Toward this end, we ask CMS to do the following:

- Identify explicitly that IVIG is statutorily excluded from the CAP and exercise discretion to exclude alpha-1 proteinase inhibitor and clotting factor too;
- Clarify that every CAP vendor must bid on at least one NDC for each single source drug and biological, even when the therapies are billed using the same HCPCS;
- Affirmatively state that that vendors do not have the authority to construct formularies;
- Ensure that medical decisions are made by physicians, not CAP vendors, and convey to carriers that LCA policies are impracticable and unnecessary in a CAP environment;
- Implement the "furnish as written" option with as minimal an administrative burden on physicians as possible;
- Allow physicians wide latitude to use the resupply option to ensure timely access to drugs and biologicals and allow physicians to request an advance supply of certain therapies to treat patients whose needs cannot be predicted;
- Focus on prospective vendors' distribution systems when defining quality standards for CAP vendors; and
- Ensure that the CAP's clerical and inventory burdens on physicians are minimal or compensate them for the increased costs of participation.

We hope our suggestions will help CMS address these important issues in the final rule. Please contact Anna Weinstein at 202-789-3100 x 2116 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Julie Birkofer

Julie Birkofer
Executive Director, North America